

This is a prototype of a mechanism that searches several CDRH databases simultaneously ([see below](#)).  
 We appreciate your feedback regarding the usefulness of this mechanism.



Prototype - for testing only

**Search CDRH Databases**

[Search Help](#)



### **Please Give Feedback**

This search mechanism searches the following CDRH databases. You may click on a link for more information about the specific database.

[PMN-510\(k\)  
Premarket  
Notification](#)

[21 CFR-Code of Federal  
Regulations Title 21](#)

[PMA-Premarket Approval](#)

[Device Listing](#)

[Establishment Registration](#)

[Products Classification](#)

[Recognized  
Consensus  
Standards](#)

[GGP-Good Guidance  
Practices](#)

[CLIA-Clinical Laboratory  
Improvement Amendments](#)

The Super Search returns the top 3 ranked results from each of these databases. You may then retrieve all of the results from any of the databases.



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)  
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

Prototype - for testing only

**Search Registration Database** [Help](#) | [Download Files](#) | [More About](#)

**Establishment Name**

**Establishment Registration Number**

**Owner/Operator Number**

**Sort by**



10

Records per Report Page

Database Updated 10/8/2002



[510\(k\)](#) | [Registration](#) | [Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [OLIA](#)  
[QFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [NHRIC](#) | [Guidance](#) | [Standards](#)

Prototype - for testing only

**Search 510(k) Database**

[Help](#) | [Download Files](#) | [More About 510\(k\)](#)

<b>Panel</b>	<input type="text"/>	
<b>510K Number</b>	<input type="text" value="K"/>	<b>Product Code</b> <input type="text"/>
<b>Applicant Name</b>	<input type="text"/>	<b>Third Party Reviewed</b> <input type="checkbox"/>
<b>Device Name</b>	<input type="text"/>	<b>Expedited Review</b> <input type="text"/>
<b>Type</b>	<input type="text"/>	
<b>Decision</b>	<input type="text"/>	
<b>Decision Date</b>	<input type="text"/> to <input type="text"/>	
<b>Sort by</b>	<input type="text" value="Decision Date (descending)"/>	

Records per Report Page

Database Updated 10/6/2002

資料(3)-1-8

市販前届出PMN-510(k)に関する情報

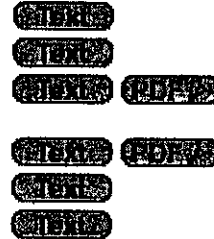
## Information on Releasable 510(k)s



- [General Information](#)
- [Federal Register Notices](#)
- [Search the Releasable 510\(k\) Database](#)
- [Listing of CDRH Substantially Equivalent \(SE\) 510\(k\) Summaries or 510\(k\) Statements, for Final Decisions Rendered](#)
- [Download 510\(k\) Files](#)

### General Information

- [510\(k\) Overview](#)
- [Class I 510\(k\) Exemptions, FDA Talk Paper - February 6, 1996](#)
- [The New 510\(k\) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](#)
- [Screening Checklist for all Premarket Notification 510\(k\) Submissions](#)
- [Reclassification Letters](#)
- [FDA Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices](#)



### Federal Register Notices

- [Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I \(2/2/98\)](#)
- [Medical Devices; Exemptions from Premarket Notification; Class II Devices \(1/21/98\)](#)



### Search the Releasable 510(k) database

You can [search the releasable 510\(k\) database](#) by Panel, 510(k) number, Product code or Device name. A search query will produce information from the database in the following format :

Device Classification Name:  
 Regulation Number:  
 510(k) Number:  
 Device Name:  
 Applicant:  
 Contact:  
Product Code:  
 Date Received:  
 Decision Date:  
Decision:  
Classification Advisory Committee:  
 Review Advisory Committee:  
 Summary or Statement

- SUMMARY indicates that a summary of safety and effectiveness information is available from FDA
- STATEMENT indicates that safety and effectiveness information may be obtained from the 510(k) applicant

### Summary/Statement/Purged Indicator:

- "Purged" indicates a 510k application released to the public under the Freedom of Information Act with trade secret/confidential commercial or privacy information exempted.

### Types:

- Traditional
- Special
- Abbreviated
- Rescission

- Evaluation of Automatic Class III Designation

Reviewed by Third Party (Y/N)  
 Expedited Review (Y/N)

**Listing of CDRH Substantially Equivalent (SE) 510(k) Summaries or 510(k) Statements, for Final Decisions Rendered.**

Listings are normally available about the 5th of each month for the prior month. Summaries are in pdf format and are available about 3 weeks after the monthly listing is posted. The 510(k) number is the indication of the link if the summary is available.

**2002 Listings**

	<a href="#"><u>November 2002</u></a>	<a href="#"><u>October 2002</u></a>
<a href="#"><u>September 2002</u></a>	<a href="#"><u>August 2002</u></a>	<a href="#"><u>July 2002</u></a>
<a href="#"><u>June 2002</u></a>	<a href="#"><u>May 2002</u></a>	<a href="#"><u>April 2002</u></a>
<a href="#"><u>March 2002</u></a>	<a href="#"><u>February 2002</u></a>	<a href="#"><u>January 2002</u></a>

**2001 Listings**

<a href="#"><u>December 2001</u></a>	<a href="#"><u>November 2001</u></a>	<a href="#"><u>October 2001</u></a>
<a href="#"><u>September 2001</u></a>	<a href="#"><u>August 2001</u></a>	<a href="#"><u>July 2001</u></a>
<a href="#"><u>June 2001</u></a>	<a href="#"><u>May 2001</u></a>	<a href="#"><u>April 2001</u></a>
<a href="#"><u>March 2001</u></a>	<a href="#"><u>February 2001</u></a>	<a href="#"><u>January 2001</u></a>

**2000 Listings**

<a href="#"><u>December 2000</u></a>	<a href="#"><u>November 2000</u></a>	<a href="#"><u>October 2000</u></a>
<a href="#"><u>September 2000</u></a>	<a href="#"><u>August 2000</u></a>	<a href="#"><u>July 2000</u></a>
<a href="#"><u>June 2000</u></a>	<a href="#"><u>May 2000</u></a>	<a href="#"><u>April 2000</u></a>
<a href="#"><u>March 2000</u></a>	<a href="#"><u>February 2000</u></a>	<a href="#"><u>January 2000</u></a>

**1999 Listings**

<a href="#"><u>December 1999</u></a>	<a href="#"><u>November 1999</u></a>	<a href="#"><u>October 1999</u></a>
<a href="#"><u>September 1999</u></a>	<a href="#"><u>August 1999</u></a>	<a href="#"><u>July 1999</u></a>
<a href="#"><u>June 1999</u></a>	<a href="#"><u>May 1999</u></a>	<a href="#"><u>April 1999</u></a>
<a href="#"><u>March 1999</u></a>	<a href="#"><u>February 1999</u></a>	<a href="#"><u>January 1999</u></a>

Listings of CDRH Substantially Equivalent (SE) 510(k) Final Decisions for months prior to 1999 can be found using the [510\(k\) Final Decision search](#). The results of the search will be in a format similar to the current monthly listings.

**Downloadable 510(k) Files**

You can download any of the following zipped files, each of which contains information about the releasable 510(k)s for the time frame indicated. Information about how to [unzip](#) these files is available. Each record in the file is 272 characters in length. These files are replaced monthly usually on the 5th of each month. In addition there is a [file description](#) and an explanation of some of the codes used in the file. You can also [download or search the Product Code Classification Database](#).

Most current month available [PMNLSTMN.ZIP](#)  
 1996-current [PMN96CUR.ZIP](#)

1991-1995  
1986-1990  
1981-1985  
1976-1980

[PMN9195.ZIP](#)  
[PMN8690.ZIP](#)  
[PMN8185.ZIP](#)  
[PMN7680.ZIP](#)

[Back To Device Evaluation Page](#)

Updated 12/5/2002

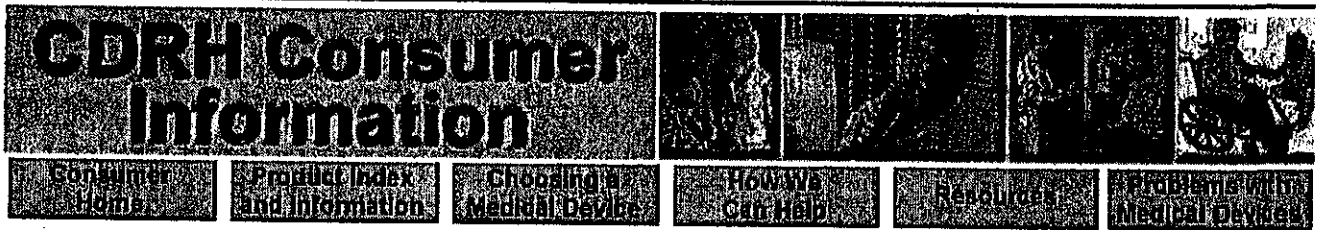
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資料(3)-1-9

承認された機器の総覧  
承認日





## Recently Approved Devices













































































































































The products listed on this page include some of the newest medical technology available. Each product listing contains information about what medical uses the device is approved for, when it can be used, and when it should not be used. This information, along with information from your doctor and other sources, can help make you an informed participant in your health care.

[List by Approval Date](#) - [List by Device Name](#) - [List by Category of Device](#)

Device Name	Category	Approv.Date	Links
Neuroform® Microdelivery Stent System	Aneurysm Repair Devices, Stents	9/11/2002	<a href="#">TEXT</a>
GlucoWatch G2 Biographer	Diabetes, Glucose Monitoring, GlucoWatch	8/28/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
IMMULITE HBsAg and IMMULITE 2000 HBsAg and Confirmatory Kit	Hepatitis	7/26/2002	<a href="#">TEXT</a>
IMMULITE <sup>®</sup> Anti-HBc IgM and IMMULITE <sup>®</sup> 2000 Anti-HBc IgM	Hepatitis	7/26/2002	<a href="#">TEXT</a>
IMMULITE <sup>®</sup> Anti-HBc and IMMULITE <sup>®</sup> 2000 Anti-HBc	Hepatitis	7/24/2002	<a href="#">TEXT</a>
IMMULITE <sup>®</sup> Anti-HBs and IMMULITE <sup>®</sup> 2000 Anti-HBs	Hepatitis	7/22/2002	<a href="#">TEXT</a>
Mentor Saline-Filled Testicular Prosthesis	Testicular Prostheses	7/19/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Siemens SONOCUR <sup>®</sup> Basic	Elbow, Extracorporeal, Shock Wave Therapy	7/19/2002	<a href="#">TEXT</a>
PALMAZ <sup>®</sup> Balloon-Expandable Stent for Renal Arteries	Angioplasty, Balloon	7/10/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
InFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device	Back Pain, Bone Graft Substitute, Spinal Fusion	7/2/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Medtronic InSync <sup>®</sup> ICD Model 7272 Dual Chamber Implantable Cardioverter Defibrillator System with Cardiac Resynchronization Therapy	Defibrillators	6/26/2002	<a href="#">TEXT</a>
AFFINITY® Cage System	Orthopedic	6/13/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Paragon CRT® (pafiufocon B), Paragon CRT-100 (pafiufocon D), Paragon Quadra RG® (pafiufocon B), and Paragon Quadra RG-100 (pafiufocon D) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy	Contact Lenses, Eye	6/13/2002	<a href="#">TEXT</a>
Roche Diagnostics Accu-Check Advantage Module	Glucose Monitoring	6/11/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
TheraSense, Inc. FreeStyle Tracker™ Diabetes Management System	Glucose Monitoring	6/11/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Indermil® Tissue Adhesive	Glue	5/22/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Guidant Cardiac Resynchronization Therapy Defibrillator System	Defibrillators	5/2/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Ancure <sup>®</sup> Aortoiliac System	Endovascular Grafts	4/24/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
INTEGRA <sup>®</sup> Dermal Regeneration Template	Burns, Collagen, Dermal, Skin	4/19/2002	<a href="#">TEXT</a>
ViewPoint CK System	Eye Surgery, Lasers	4/11/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
AMPLATZER <sup>®</sup> PFO Occluder	Heart Devices, Occlusion Devices, Septal Occluders	4/5/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
IntraCoil <sup>®</sup> Self-Expanding Peripheral Stent	Stents	4/3/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
QuickSeal Arterial Closure System	Heart, Heart Devices, Sealants	3/25/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
Disintegrator Insulin Needle Destruction Unit	Needles, Sharps	3/15/2002	<a href="#">TEXT</a> <a href="#">PDF</a>

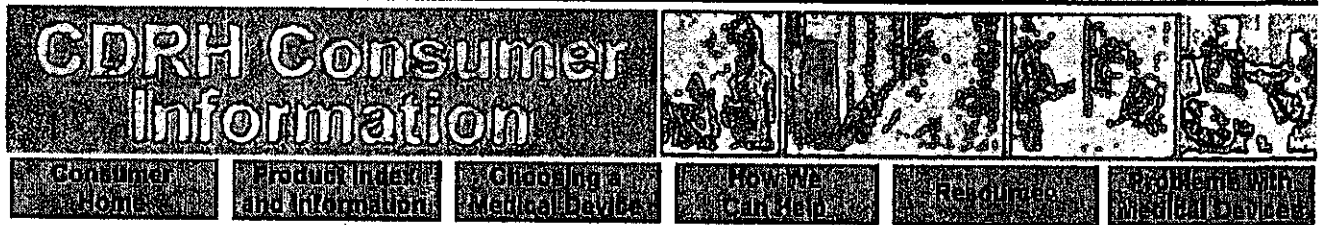
Lorad Digital Breast Imager	Breast Imaging Devices, Digital Mammography	3/15/2002	TEXT	PDF
Lea's Shield	Contraceptives, Women's Health	3/14/2002	TEXT	PDF
SIR-Spheres <sup>®</sup>	Cancer, Radioactive Spheres	3/5/2002	TEXT	PDF
Elecsys Anti-HBs Immunoassay and Elecsys PreciControl Anti-HBs	Hepatitis	2/27/2002	TEXT	PDF
Wartner Wart Removal System	Wart Removal	2/20/2002	TEXT	PDF
Second Look™	Breast Imaging Devices, Digital Mammography	1/31/2002	TEXT	PDF
Dornier Epos Ultra	Shock Wave Therapy	1/15/2002	TEXT	PDF
MammoReader	Breast Imaging Devices, Mammography	1/15/2002	TEXT	PDF
Activa <sup>®</sup> Parkinson's Control System	Brain Stimulator, Parkinson's Disease, Stimulator	1/14/2002	TEXT	PDF
VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method	Excimer Lasers	12/19/2001	TEXT	PDF
Acticon™ Neosphincter	Artificial Sphincter	12/18/2001	TEXT	PDF
LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System	Defibrillators	12/18/2001	TEXT	PDF
CoSeal™ Surgical Sealant	Sealants	12/14/2001	TEXT	PDF
AMPLATZER <sup>®</sup> Septal Occluder	Cardiac, Heart, Heart Devices	12/5/2001	TEXT	PDF
NNMT Medical, Inc. CardioSEAL Septal Occlusion System with QwikLoad	Septal Occluders	12/5/2001	TEXT	PDF
BioGlue Surgical Adhesive	Glue	12/3/2001	TEXT	PDF
QuantIFERON <sup>®</sup> -TB	Tuberculosis	11/28/2001	TEXT	PDF
Genesis Neurostimulation (IPG) System	Stimulator	11/21/2001	TEXT	PDF
Ascension MCP	Finger Joint Implant, Orthopedic	11/19/2001	TEXT	PDF
Gynecare Intergel Adhesion Prevention Solution	Adhesion Prevention, Ob/Gyn, Ob/Gyn Surgical Devices	11/16/2001	TEXT	PDF
WALLSTENT Venous Endoprosthesis with Unistep	Cardiac	11/16/2001	TEXT	PDF
IMMULITE AFP and IMMULTE 2000 AFP	Alpha-Fetoprotein	11/9/2001	TEXT	PDF
OP-1™ TM Implant	Bone Implant, Collagen	10/17/2001	TEXT	PDF
Focus Night and Day Soft Contact Lens	Contact Lenses	10/11/2001	TEXT	PDF
Home Monitoring System with the BA03 DDDR Pulse Generator	Pacemaker, Pacing Systems	10/11/2001	TEXT	PDF
DERMAGRAFT	Skin, Skin Substitutes, Wound Healing Devices	9/28/2001	TEXT	PDF
SenoScan Full Field Digital Mammography System	Mammography	9/25/2001	TEXT	PDF
Deflux Injectable Gel	Urology, Vesicoureteral Reflux	9/24/2001	TEXT	PDF
Model 3100B High-Frequency Oscillatory Ventilator	Ventilators	9/24/2001	TEXT	PDF
SOUNDTEC <sup>®</sup> Direct Drive Hearing System	Hearing Devices	9/7/2001	TEXT	PDF
OrCel Bilayered Cellular Matrix	Wound and Burn Dressing	8/31/2001	TEXT	PDF
Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	Hepatitis	8/30/2001	TEXT	PDF
Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis	Finger Joint Implant, Protheses	8/28/2001	TEXT	PDF
Medtronic InSync Biventricular Pacing System including the InSync Model 8040 Pulse Generator, Attain LV Model 2187 and Attain CS Model 2188 Leads	Pacemaker, Pacing Systems	8/28/2001	TEXT	PDF
MED-EL COMBI 40+ Cochlear Implant System	Hearing Devices	8/20/2001	TEXT	PDF
Given Diagnostic Imaging System	Camera, Diagnostic Imaging, Endoscopy	8/1/2001	TEXT	PDF
UBIS 5000 Ultrasound Bone Sonometer	Bone Sonometers, Orthopedic, Ultrasound	7/17/2001	TEXT	PDF
AquaFlow Collagen Glaucoma Drainage Device - Model CGDD-20	Glaucoma Devices	7/12/2001	TEXT	PDF

RapidScreen RS-2000	Computer Aided Diagnosis (CADx), Lung Cancer, X-Rays	7/12/2001		
Integrity AFx DR Model 5346	Pacemaker, Pacing Systems	7/11/2001		
AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	Hepatitis	7/5/2001		
Dimension RxL PSA Flex Reagent Cartridge	Prostate, PSA	7/5/2001		
COBAS AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	Hepatitis	7/3/2001		
TMx-2000 BPH ThermoTherapy System	Microwaves, Prostate	6/29/2001		
Carisolv Non-Invasive Caries Removal System	Dental Composites	6/27/2001		
Diagnostic Products Corporation Total Prostate Specific Antigen (PSA) Assays on the Immulite and Immulite 2000 Analyzers	Prostate	6/19/2001		
AMS Sphincter 800-Urinary Prosthesis	Incontinence, Prostate, Prostate Surgery	6/14/2001		
LAP-Band Adjustable Gastric Banding (LAGB) System	Gastric Banding, Lap-Band, Obesity, Stomach Band, Weight Loss Devices	6/5/2001		
Elecsys HBsAg Immunoassay, Elecsys HBsAg Confirmatory, and PreciControl HBsAg	Hepatitis	6/1/2001		
On-X Prosthetic Heart Valve	Heart, Heart Devices, Heart Valve	5/30/2001		
Heartstream FR2 AED with Attenuated Defibrillation Pads	Automated External Defibrillators (AED), Defibrillators	5/2/2001		
Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit	Hepatitis	4/27/2001		
BAK/Cervical (BAK/C) Interbody Fusion System	Orthopedic, Spinal Fusion	4/20/2001		
HerOption Uterine Cryoblation Therapy System	Ablation Devices, Cryoblation	4/20/2001		
Hydro ThermAblator	Ablation Devices, Endometrial	4/20/2001		
STAARVISC Sodium Hyaluronate	Eye Surgery, Sodium Hyaluronate	4/18/2001		
Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System (supplement)	Defibrillators	4/6/2001		
CeeOn Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens - Model 911A	Intraocular Lens (IOL)	4/5/2001		
Devices for Testing the Hepatitis B Virus (HBV)	Diagnostic Tests, Hepatitis	3/30/2001		
PROSTALAC Hip Temporary Prosthesis	Hip Prostheses	3/23/2001		
GlucoWatch Automatic Glucose Biographer	Blood Glucose Monitors, Diabetes, Glucose Monitoring, Glucowatch	3/22/2001		
N Latex Cystatin C Test Kit	Cystatin C, Diagnostic Tests, In Vitro Diagnostics (IVD)	3/13/2001		
Edwards Prima Plus Stentless Bioprosthesis Model 2500P	Heart, Heart Devices, Heart Valve	2/27/2001		
TMJ Fossa Eminence Prosthesis	Jaw Surgery, Temporomandibular Joint, Temporomandibular Joint (TMJ) Implants	2/27/2001		
Composite Cultured Skin (CCS)	Collagen, Skin, Skin Grafts, Wound Healing Devices	2/21/2001		
VISTAKON (Ieneficon A) Soft Contact Lenses	Contact Lenses	2/16/2001		
Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring	Fetal Oxygen, Monitors	2/9/2001		
SUPARTZ Dispo	Sodium Hyaluronate	1/24/2001		
TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prostheses System	Temporomandibular Joint (TMJ) Implants	1/5/2001		
Microny SR+ Cardiac Pacemaker (Model 245T)	Pacemaker, Pacing Systems	12/21/2000		
Q-103 Needle Management System	Anti-Needlestick Devices, Diabetes, Glucose Monitoring, Hypodermic Needles, Needles, Sharps	12/21/2000		
Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	Analyzer Systems, Prostate, Prostate Cancer, PSA	12/12/2000		
Psychemedics Corporation Opiate Assay	Diagnostic Tests, Drugs of Abuse,	12/11/2000		

Stinger Ablation Catheter and TempLink Extension Cable	Test Kits			
PATHWAY -Her 2 (Clone CB11)	Ablation Devices, Catheters	11/29/2000		
Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	Cancer, In Vitro Diagnostics (IVD)	11/28/2000		
Optical Biopsy System	Analyzer Systems, Prostate, Prostate Cancer, PSA	11/22/2000		
Cordis Checkmate System	Biopsy Devices, Cancer	11/14/2000		
Novoste Beta-Cath System	Angioplasty, Brachytherapy, Heart, Heart Devices, Restenosis	11/3/2000		
Photon DR Implantable Cardioverter Defibrillator	Angioplasty, Brachytherapy, Heart, Heart Devices, Restenosis	11/3/2000		
Nucleus 24 Auditory Brainstem Implant System	Defibrillators	10/27/2000		
BeStent-2 with Discrete Technology Over-The-Wire and Rapid Exchange Coronary Stent Delivery Systems	Auditory Implant, Brain Stimulator, Hearing Devices, Stimulator	10/20/2000		
ATS Open Pivot Bileaflet Heart Valve	Angioplasty, Stents	10/16/2000		
OssaTron	Heart, Heart Devices, Heart Valve	10/13/2000		
BiodivYsio AS PC (phosphorylcholine) Coated Stent Delivery System	Orthopedic, Shock Wave Therapy	10/12/2000		
Phylax AV Implantable Cardioverter Defibrillator with Program Software	Stents	9/29/2000		
Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators	Defibrillators, Heart, Heart Devices	9/29/2000		
TRUFILL <sub>n</sub> n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System	Calibrators, In Vitro Diagnostics (IVD)	9/29/2000		
DTU-One Ultrasound Scanner	Embolization, Occlusion Devices	9/25/2000		
Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay - P990055	Bone Sonometers	9/19/2000		
Medstone STS Lithotripter	Analyzer Systems, Prostate, PSA	9/8/2000		
Vibrant Soundbridge	Lithotripters	9/5/2000		
Horizon 55 EW and Horizon 55 EW Westint Contact Lenses	Hearing Devices	8/31/2000		
QUS-2 Calcaneal Ultrasonometer	Contact Lenses	8/22/2000		
Medtronic IsoMed Constant Flow Infusion System	Bone Sonometers	8/8/2000		
Mentor Alpha I Inflatable Penile Prosthesis	Infusion, Infusion Pumps, Pumps	7/21/2000		
Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral)	Penile Devices	7/14/2000		
Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens	Heart Valve	7/14/2000		
Diomed 630 PDT Laser Model T2USA	Contact Lenses	7/11/2000		
Hyperion LTK System	Cancer, Lasers	6/30/2000		
Vascular Solutions Duett Sealing Device	Eye Surgery, Lasers	6/30/2000		
NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	Balloon, Sealants	6/22/2000		
Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System	Ablation Devices, Catheters, Heart, Heart Devices, Radiofrequency Ablation	6/15/2000		
CoStasis/DynaStat Surgical Hemostat	Defibrillators	6/14/2000		
Stocker 70 RF Generator	Hemostat	6/13/2000		
FocalSeal-Synthetic Absorbable Sealant	Ablation Devices, Radiofrequency Ablation	5/31/2000		
OxiFirst Fetal Oxygen Saturation Monitoring System	Sealants	5/26/2000		
	Fetal Oxygen, Monitors, Oxygen	5/12/2000		

資料(3)-1-10

承認された機器総覧の機器名



**Recently Approved Devices**



The products listed on this page include some of the newest medical technology available. Each product listing contains information about what medical uses the device is approved for, when it can be used, and when it should not be used. This information, along with information from your doctor and other sources, can help make you an informed participant in your health care.

List by Approval Date – List by Device Name – List by Category of Device

Device Name	Category	Approv.Date	Links
Action™ Neosphincter	Artificial Sphincter	12/18/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Activæ Parkinson's Control System	Brain Stimulator, Parkinson's Disease, Stimulator	1/14/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
AFFINITY-Cage System	Orthopedic	6/13/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
AMPLATZER® PFO Occluder	Heart Devices, Occlusion Devices, Septal Occluders	4/5/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
AMPLATZER® Septal Occluder	Cardiac, Heart, Heart Devices	12/5/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	Hepatitis	7/5/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
AMS Sphincter 800-Urinary Prosthesis	Incontinence, Prostate, Prostate Surgery	6/14/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Ancure® Aortoiliac System	Endovascular Grafts	4/24/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
AquaFlow Collagen Glaucoma Drainage Device – Model CGDD-20	Glaucoma Devices	7/12/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Ascension MCP	Finger Joint Implant, Orthopedic	11/19/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
ATS Open Pivot Bileaflet Heart Valve	Heart, Heart Devices, Heart Valve	10/13/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis	Finger Joint Implant, Prostheses	8/28/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
BAK/Cervical (BAK/C) Interbody Fusion System	Orthopedic, Spinal Fusion	4/20/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay – P990055	Analyzer Systems, Prostate, PSA	9/8/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
BeStent-2 with Discrete Technology-Over-The-Wire and Rapid Exchange Coronary Stent Delivery Systems	Angioplasty, Stents	10/16/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
Biodivysio AS PC (phosphorylcholine) Coated Stent Delivery System	Stents	9/29/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
BioGlue Surgical Adhesive	Glue	12/3/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Carisolv Non-Invasive Caries Removal System	Dental Composites	6/27/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
CeeOn Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens – Model 911A	Intraocular Lens (IOL)	4/5/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
COBAS AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	Hepatitis	7/3/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Composite Cultured Skin (CCS)	Collagen, Skin, Skin Grafts, Wound Healing Devices	2/21/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
Cordis Checkmate System	Angioplasty, Brachytherapy, Heart, Heart Devices, Restenosis	11/3/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring	Fetal Oxygen, Monitors	2/9/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
CoSeal™ Surgical Sealant	Sealants	12/14/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
CoStasis/DynaStat Surgical Hemostat	Hemostat	6/13/2000	<a href="#">TEXT</a> <a href="#">PDF</a>

Deflux Injectable Gel	Urology, Vesicoureteral Reflux	9/24/2001	TEXT	PDF
DERMAGRAFT	Skin, Skin Substitutes, Wound Healing Devices	9/28/2001	TEXT	PDF
Devices for Testing the Hepatitis B Virus (HBV)	Diagnostic Tests, Hepatitis	3/30/2001	TEXT	PDF
Diagnostic Products Corporation Total Prostate Specific Antigen (PSA) Assays on the Immulite and Immulite 2000 Analyzers	Prostate	6/19/2001	TEXT	PDF
Dimension RxL PSA Flex Reagent Cartridge	Prostate, PSA	7/5/2001	TEXT	PDF
Diomed 630 PDT Laser Model T2USA	Cancer, Lasers	6/30/2000	TEXT	PDF
Disintegrator Insulin Needle Destruction Unit	Needles, Sharps	3/15/2002	TEXT	PDF
Domier Epos Ultra	Shock Wave Therapy	1/15/2002	TEXT	PDF
DTU-One Ultrasound Scanner	Bone Sonometers	9/19/2000	TEXT	PDF
Edwards Prima Plus Stentless Bioprosthesis Model 2500P	Heart, Heart Devices, Heart Valve	2/27/2001	TEXT	PDF
Elecsys Anti-HBs Immunoassay and Elecsys PreciControl Anti-HBs	Hepatitis	2/27/2002	TEXT	PDF
Elecsys HBsAg Immunoassay, Elecsys HBsAg Confirmatory, and PreciControl HBsAg	Hepatitis	6/1/2001	TEXT	PDF
FocalSeal-Synthetic Absorbable Sealant	Sealants	5/28/2000	TEXT	PDF
Focus Night and Day Soft Contact Lens	Contact Lenses	10/11/2001	TEXT	PDF
Genesis Neurostimulation (IPG) System	Stimulator	11/21/2001	TEXT	PDF
Given Diagnostic Imaging System	Camera, Diagnostic Imaging, Endoscopy	8/1/2001	TEXT	PDF
GlucoWatch Automatic Glucose Biographer	Blood Glucose Monitors, Diabetes, Glucose Monitoring, GlucoWatch	3/22/2001	TEXT	PDF
GlucoWatch G2 Biographer	Diabetes, Glucose Monitoring, GlucoWatch	8/26/2002	TEXT	PDF
Guidant Cardiac Resynchronization Therapy Defibrillator System	Defibrillators	5/2/2002	TEXT	PDF
Gynecare Intergel Adhesion Prevention Solution	Adhesion Prevention, Ob/Gyn, Ob/Gyn Surgical Devices	11/16/2001	TEXT	PDF
Heartstream FR2 AED with Attenuated Defibrillation Pads	Automated External Defibrillators (AED), Defibrillators	5/2/2001	TEXT	PDF
HerOption Uterine Cryoblation Therapy System	Ablation Devices, Cryoblation	4/20/2001	TEXT	PDF
Home Monitoring System with the BA03 DDDR Pulse Generator	Pacemaker, Pacing Systems	10/11/2001	TEXT	PDF
Horizon 55 EW and Horizon 55 EW Westint Contact Lenses	Contact Lenses	8/22/2000	TEXT	PDF
Hydro ThermAblator	Ablation Devices, Endometrial	4/20/2001	TEXT	PDF
Hyperion LTK System	Eye Surgery, Lasers	6/30/2000	TEXT	PDF
IMMULITE AFP and IMMULITE 2000 AFP	Alpha-Fetoprotein	11/9/2001	TEXT	PDF
IMMULITE HBsAg and IMMULITE 2000 HBsAg and Confirmatory Kit	Hepatitis	7/26/2002	TEXT	
IMMULITE <sub>3</sub> Anti-HBc and IMMULITE <sub>3</sub> 2000 Anti-HBc	Hepatitis	7/24/2002	TEXT	
IMMULITE <sub>3</sub> Anti-HBc IgM and IMMULITE <sub>3</sub> 2000 Anti-HBc IgM	Hepatitis	7/26/2002	TEXT	
IMMULITE <sub>3</sub> Anti-HBs and IMMULITE <sub>3</sub> 2000 Anti-HBs	Hepatitis	7/22/2002	TEXT	
Indermil-Tissue Adhesive	Glue	5/22/2002	TEXT	PDF
inFUSE-Bone Graft/LT-CAGE-Lumbar Tapered Fusion Device	Back Pain, Bone Graft Substitute, Spinal Fusion	7/2/2002	TEXT	PDF
INTEGRA <sub>3</sub> Dermal Regeneration Template	Burns, Collagen, Dermal, Skin	4/19/2002	TEXT	
Integrity AFx DR Model 5346	Pacemaker, Pacing Systems	7/11/2001	TEXT	PDF
IntraCoil <sub>3</sub> Self-Expanding Peripheral Stent	Stents	4/3/2002	TEXT	PDF
LAP-Band <sub>3</sub> Adjustable Gastric Banding (LAGB <sub>3</sub> ) System	Gastro Banding, Lap-Band, Obesity, Stomach Band, Weight Loss Devices	6/5/2001	TEXT	PDF
Lea's Shield	Contraceptives, Women's Health	3/14/2002	TEXT	PDF
	Defibrillators			

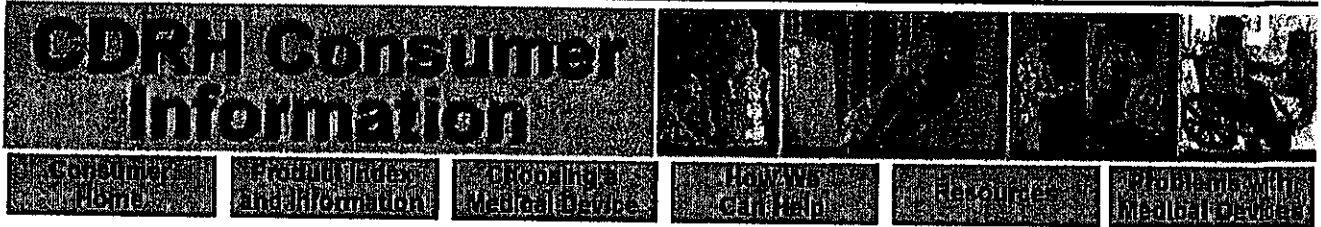
LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System		12/18/2001	TEXT	PDF
Lorad Digital Breast Imager	Breast Imaging Devices, Digital Mammography	3/15/2002	TEXT	PDF
MammoReader	Breast Imaging Devices, Mammography	1/15/2002	TEXT	PDF
MED-EL COMBI 40+ Cochlear Implant System	Hearing Devices	8/20/2001	TEXT	PDF
Medstone STS Lithotripter	Lithotripters	9/5/2000	TEXT	PDF
Medtronic InSync Biventricular Pacing System including the InSync Model 8040 Pulse Generator, Attain LV Model 2187 and Attain CS Model 2188 Leads	Pacemaker, Pacing Systems	8/28/2001	TEXT	PDF
Medtronic IsoMed Constant Flow Infusion System	Infusion, Infusion Pumps, Pumps	7/21/2000	TEXT	PDF
Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System	Defibrillators	6/14/2000	TEXT	PDF
Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System (supplement)	Defibrillators	4/6/2001	TEXT	PDF
Medtronic InSync ICD Model 7272 Dual Chamber Implantable Cardioverter Defibrillator System with Cardiac Resynchronization Therapy	Defibrillators	6/26/2002	TEXT	
Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens	Contact Lenses	7/11/2000	TEXT	PDF
Mentor Alpha I Inflatable Penile Prosthesis	Penile Devices	7/14/2000	TEXT	PDF
Mentor Saline-Filled Testicular Prosthesis	Testicular Prostheses	7/19/2002	TEXT	PDF
Microny SR+ Cardiac Pacemaker (Model 245T)	Pacemaker, Pacing Systems	12/21/2000	TEXT	PDF
Model 3100B High-Frequency Oscillatory Ventilator	Ventilators	9/24/2001	TEXT	PDF
Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral)	Heart Valve	7/14/2000	TEXT	PDF
N Latex Cystatin C Test Kit	Cystatin C, Diagnostic Tests, In Vitro Diagnostics (IVD)	3/13/2001	TEXT	PDF
NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	Ablation Devices, Catheters, Heart, Heart Devices, Radiofrequency Ablation	6/15/2000	TEXT	PDF
Neuroform Microdelivery Stent System	Aneurysm Repair Devices, Stents	9/11/2002	TEXT	
NNMT Medical, Inc. CardioSEAL Septal Occlusion System with QwikLoad	Septal Ocluders	12/5/2001	TEXT	PDF
Novoste Beta-Cath System	Angioplasty, Brachytherapy, Heart, Heart Devices, Restenosis	11/3/2000	TEXT	PDF
Nucleus 24 Auditory Brainstem Implant System	Auditory Implant, Brain Stimulator, Hearing Devices, Stimulator	10/20/2000	TEXT	PDF
On-X Prosthetic Heart Valve	Heart, Heart Devices, Heart Valve	5/30/2001	TEXT	PDF
OP-1 TM Implant	Bone Implant, Collagen	10/17/2001	TEXT	PDF
Optical Biopsy System	Biopsy Devices, Cancer	11/14/2000	TEXT	PDF
OrCel Bilayered Cellular Matrix	Wound and Burn Dressing	8/31/2001	TEXT	PDF
OssaTron	Orthopedic, Shock Wave Therapy	10/12/2000	TEXT	PDF
OxiFirst Fetal Oxygen Saturation Monitoring System	Fetal Oxygen, Monitors, Oxygen	5/12/2000	TEXT	PDF
PALMAZ Balloon-Expandable Stent for Renal Arteries	Angioplasty, Balloon	7/10/2002	TEXT	PDF
Paragon CRT (pafufocon B), Paragon CRT-100 (pafufocon D), Paragon Quadra RG (pafufocon B), and Paragon Quadra RG-100 (pafufocon D) Rigid Gas Permeable Contact Lenses for Corneal Refractive Therapy	Contact Lenses, Eye	6/13/2002	TEXT	
PATHWAY -Her 2 (Clone CB11)	Cancer, In Vitro Diagnostics (IVD)	11/28/2000	TEXT	PDF
Photon DR Implantable Cardioverter Defibrillator	Defibrillators	10/27/2000	TEXT	PDF
Phylax AV Implantable Cardioverter Defibrillator with Program Software	Defibrillators, Heart, Heart Devices	9/29/2000	TEXT	PDF
PROSTALAC Hip Temporary Prosthesis	Hip Prostheses	3/23/2001	TEXT	PDF
Psychomedics Corporation Opiate Assay	Diagnostic Tests, Drugs of Abuse, Test Kits	12/11/2000	TEXT	PDF
Q-103 Needle Management System	Anti-Needlestick Devices,	12/21/2000	TEXT	PDF



QuantIFERON <sub>3</sub> -TB	Diabetes, Glucose Monitoring, Hypodermic Needles, Needles, Sharps			
QuickSeal Arterial Closure System	Tuberculosis	11/28/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
QUS-2 Calcaneal Ultrasonometer	Heart, Heart Devices, Sealants	3/25/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
RapidScreen RS-2000	Bone Sonometers	8/8/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
Roche Diagnostics Accu-Check Advantage Module	Computer Aided Diagnosis (CADx), Lung Cancer, X-Rays	7/12/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	Glucose Monitoring	6/11/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	Analyzer Systems, Prostate, Prostate Cancer, PSA	12/12/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
Second Look <sup>TM</sup>	Analyzer Systems, Prostate, Prostate Cancer, PSA	11/22/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
SenoScan Full Field Digital Mammography System	Breast Imaging Devices, Digital Mammography	1/31/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
Siemens SONOCUR <sub>3</sub> Basic	Mammography	9/25/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
SIR-Spheres <sub>3</sub>	Elbow, Extracorporeal, Shock Wave Therapy	7/19/2002	<a href="#">TEXT</a>	
SOUNDTEC <sub>3</sub> Direct Drive Hearing System	Cancer, Radioactive Spheres	3/5/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
STAARVISC Sodium Hyaluronate	Hearing Devices	9/7/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Stinger Ablation Catheter and TempLink Extension Cable	Eye Surgery, Sodium Hyaluronate	4/18/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Stocker 70 RF Generator	Ablation Devices, Catheters	11/29/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
SUPARTZ Dispo	Ablation Devices, Radiofrequency Ablation	5/31/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
TheraSense, Inc. FreeStyle Tracker <sup>TM</sup> Diabetes Management System	Sodium Hyaluronate	1/24/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prosthesis System	Glucose Monitoring	6/11/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
TMJ Fossa Eminence Prosthesis	Temporomandibular Joint (TMJ) Implants	1/5/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
TMx-2000 BPH ThermoTherapy System	Jaw Surgery, Temporomandibular Joint, Temporomandibular Joint (TMJ) Implants	2/27/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
TRUFILL <sub>3</sub> n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System	Microwaves, Prostate	6/29/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
UBIS 5000 Ultrasound Bone Sonometer	Embolization, Occlusion Devices	9/25/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
Vascular Solutions Duett Sealing Device	Bone Sonometers, Orthopedic, Ultrasound	7/17/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Vibrant Soundbridge	Balloon, Sealants	6/22/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
ViewPoint OK System	Hearing Devices	8/31/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
VISTAKON (Ienefilcon A) Soft Contact Lenses	Eye Surgery, Lasers	4/11/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>
VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method	Contact Lenses	2/16/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators	Excimer Lasers	12/19/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	Calibrators, In Vitro Diagnostics (IVD)	9/29/2000	<a href="#">TEXT</a>	<a href="#">PDF</a>
Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit	Hepatitis	8/30/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
WALLSTENT Venous Endoprosthesis with Unistep	Hepatitis	4/27/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
Wartner Wart Removal System	Cardio	11/16/2001	<a href="#">TEXT</a>	<a href="#">PDF</a>
	Wart Removal	2/20/2002	<a href="#">TEXT</a>	<a href="#">PDF</a>

資料(3)-1-11

承認された機器の総覧  
機器のカテゴリ


























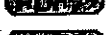


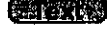










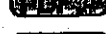
## Recently Approved Devices



The products listed on this page include some of the newest medical technology available. Each product listing contains information about what medical uses the device is approved for, when it can be used, and when it should not be used. This information, along with information from your doctor and other sources, can help make you an informed participant in your health care.

[List by Approval Date](#) – [List by Device Name](#) – [List by Category of Device](#)

Device Name	Approv.Date	Links
<b>Ablation Devices</b>		
▶ HerOption Uterine Cryoblation Therapy System	4/20/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Hydro ThermAblator	4/20/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	6/15/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Stinger Ablation Catheter and TempLink Extension Cable	11/29/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Stocker 70 RF Generator	5/31/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
<b>Adhesion Prevention</b>		
▶ Gynecare Intergel Adhesion Prevention Solution	11/16/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
<b>Alpha-Fetoprotein</b>		
▶ IMMULITE AFP and IMMULTE 2000 AFP	11/9/2001	<a href="#">TEXT</a> <a href="#">PDF</a>
<b>Analyzer Systems</b>		
▶ Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay – P990055	9/8/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	12/12/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	11/22/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
<b>Aneurysm Repair Devices</b>		
▶ Neuroform Microdelivery Stent System	9/11/2002	<a href="#">TEXT</a>
<b>Angioplasty</b>		
▶ BeStent-2 with Discrete Technology Over-The-Wire and Rapid Exchange Coronary Stent Delivery Systems	10/16/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Cordis Checkmate System	11/3/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ Novoste Beta-Cath System	11/3/2000	<a href="#">TEXT</a> <a href="#">PDF</a>
▶ PALMAZ Balloon-Expandable Stent for Renal Arteries	7/10/2002	<a href="#">TEXT</a> <a href="#">PDF</a>
<b>Anti-Needlestick Devices</b>		
▶ Q-103 Needle Management System	12/21/2000	<a href="#">TEXT</a> <a href="#">PDF</a>

<b>Artificial Sphincter</b>			
▶ Acticon™ Neosphincter	12/18/2001		
<b>Auditory Implant</b>			
▶ Nucleus 24 Auditory Brainstem Implant System	10/20/2000		
<b>Automated External Defibrillators (AED)</b>			
▶ Heartstream FR2 AED with Attenuated Defibrillation Pads	5/2/2001		
<b>Back Pain</b>			
▶ InFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device	7/2/2002		
<b>Balloon</b>			
▶ PALMAZ® Balloon-Expandable Stent for Renal Arteries	7/10/2002		
▶ Vascular Solutions Duett Sealing Device	6/22/2000		
<b>Biopsy Devices</b>			
▶ Optical Biopsy System	11/14/2000		
<b>Blood Glucose Monitors</b>			
▶ GlucoWatch Automatic Glucose Biographer	3/22/2001		
<b>Bone Graft Substitute</b>			
▶ InFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device	7/2/2002		
<b>Bone Implant</b>			
▶ OP-1™ TM Implant	10/17/2001		
<b>Bone Sonometers</b>			
▶ DTU-One Ultrasound Scanner	9/19/2000		
▶ QUS-2 Calcaneal Ultrasonometer	8/8/2000		
▶ UBIS 5000 Ultrasound Bone Sonometer	7/17/2001		
<b>Brachytherapy</b>			
▶ Cordis Checkmate System	11/3/2000		
▶ Novoste Beta-Cath System	11/3/2000		
<b>Brain Stimulator</b>			
▶ Activa® Parkinson's Control System	1/14/2002		
▶ Nucleus 24 Auditory Brainstem Implant System	10/20/2000		
<b>Breast Imaging Devices</b>			
▶ Lorad Digital Breast Imager	3/15/2002		
▶ MammoReader	1/15/2002		
▶ Second Look™	1/31/2002	