














Burns			
▶ INTEGRA ³ Dermal Regeneration Template	4/19/2002	TEXT	PDF
Calibrators			
▶ Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators	9/29/2000	TEXT	PDF
Camera			
▶ Given Diagnostic Imaging System	8/1/2001	TEXT	PDF
Cancer			
▶ Diomed 630 PDT Laser Model T2USA	6/30/2000	TEXT	PDF
▶ Optical Biopsy System	11/14/2000	TEXT	PDF
▶ PATHWAY [®] Her 2 (Clone CB11)	11/28/2000	TEXT	PDF
▶ SIR-Spheres ³	3/5/2002	TEXT	PDF
Cardiac			
▶ AMPLATZER ³ Septal Occluder	12/5/2001	TEXT	PDF
▶ WALLSTENT Venous Endoprosthesis with Unistep	11/16/2001	TEXT	PDF
Catheters			
▶ NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	6/15/2000	TEXT	PDF
▶ Stinger Ablation Catheter and TempLink Extension Cable	11/29/2000	TEXT	PDF
Collagen			
▶ Composite Cultured Skin (CCS)	2/21/2001	TEXT	PDF
▶ INTEGRA ³ Dermal Regeneration Template	4/19/2002	TEXT	
▶ OP-1 TM Implant	10/17/2001	TEXT	PDF
Computer Aided Diagnosis (CADx)			
▶ RapidScreen RS-2000	7/12/2001	TEXT	PDF
Contact Lenses			
▶ Focus Night and Day Soft Contact Lens	10/11/2001	TEXT	PDF
▶ Horizon 55 EW and Horizon 55 EW Westint Contact Lenses	8/22/2000	TEXT	PDF
▶ Menicon Z (tisilfocon A) Rigid Gas Permeable Contact Lens	7/11/2000	TEXT	PDF
▶ 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	6/13/2002	TEXT	
▶ VISTAKON (lenefiloon A) Soft Contact Lenses	2/16/2001	TEXT	PDF
Contraceptives			
▶ Lea's Shield	3/14/2002	TEXT	PDF
Cryoblation			
▶ HerOption Uterine Cryoblation Therapy System	4/20/2001	TEXT	PDF
Cystatin C			
▶ N Latex Cystatin C Test Kit	3/13/2001	TEXT	PDF



Defibrillators

- ▶ Guidant Cardiac Resynchronization Therapy Defibrillator System 5/2/2002  
- ▶ Heartstream FR2 AED with Attenuated Defibrillation Pads 5/2/2001  
- ▶ LIFECOR Wearable Cardioverter Defibrillator (WCD®) 2000 System 12/18/2001  
- ▶ Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System 6/14/2000  
- ▶ Medtronic Model 7250 Jewel AF Implantable Cardioverter Defibrillator System (supplement) 4/8/2001  
- ▶ Medtronic InSync ICD Model 7272 Dual Chamber Implantable Cardioverter Defibrillator System with Cardiac Resynchronization Therapy 6/26/2002 
- ▶ Photon DR Implantable Cardioverter Defibrillator 10/27/2000  
- ▶ Phylax AV Implantable Cardioverter Defibrillator with Program Software 9/29/2000  

Dental Composites

- ▶ Carisolv Non-Invasive Caries Removal System 6/27/2001  

Dermal

- ▶ INTEGRA Dermal Regeneration Template 4/19/2002 






Diabetes

- ▶ GlucoWatch Automatic Glucose Biographer 3/22/2001  
- ▶ GlucoWatch G2 Biographer 8/28/2002  
- ▶ Q-103 Needle Management System 12/21/2000  


Diagnostic Imaging

- ▶ Given Diagnostic Imaging System 8/1/2001  

Diagnostic Tests

- ▶ Devices for Testing the Hepatitis B Virus (HBV) 3/30/2001  
- ▶ N Latex Cystatin C Test Kit 3/13/2001  
- ▶ Psychoedics Corporation Opiate Assay 12/11/2000  

Digital Mammography

- ▶ Lorad Digital Breast Imager 3/15/2002  
- ▶ Second Look™ 1/31/2002  



Drugs of Abuse

- ▶ Psychoedics Corporation Opiate Assay 12/11/2000  


Elbow

- ▶ Siemens SONOCUR Basic 7/19/2002 

Embolization

- ▶ TRUFILL n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System 9/25/2000  

Endometrial

- ▶ Hydro ThermAblator 4/20/2001  



Endoscopy

▶ Given Diagnostic Imaging System 8/1/2001

Endovascular Grafts

▶ Ancure[®] Aortoiliac System 4/24/2002

Excimer Lasers

▶ VISX Excimer Laser System and Custom Contoured Ablation Pattern (C-CAP) Method 12/19/2001

Extracorporeal

▶ Siemens SONOCUR[®] Basic 7/19/2002

Eye

▶ 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 6/13/2002

Eye Surgery

▶ Hyperion LTK System 6/30/2000

▶ STAARVISC Sodium Hyaluronate 4/18/2001

▶ ViewPoint CK System 4/11/2002

Fetal Oxygen

▶ Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring 2/9/2001

▶ OxiFirst Fetal Oxygen Saturation Monitoring System 5/12/2000

Finger Joint Implant

▶ Ascension MCP 11/19/2001

▶ Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis 8/28/2001

Gastric Banding

▶ LAP-Band[®] Adjustable Gastric Banding (LAGB[®]) System 6/5/2001

Glaucoma Devices

▶ AquaFlow Collagen Glaucoma Drainage Device - Model CGDD-20 7/12/2001

Glucose Monitoring

▶ GlucoWatch Automatic Glucose Biographer 3/22/2001

▶ GlucoWatch G2 Biographer 8/26/2002

▶ Q-103 Needle Management System 12/21/2000

▶ Roche Diagnostics Accu-Check Advantage Module 6/11/2002

▶ TheraSense, Inc. FreeStyle Tracker[™] Diabetes Management System 6/11/2002

Glucowatch

▶ GlucoWatch Automatic Glucose Biographer 3/22/2001


▶ GlucoWatch G2 Biographer	8/26/2002	STARD	FDPEP
Glue			
▶ BioGlue Surgical Adhesive	12/3/2001	STARD	FDPEP
▶ Indermil Tissue Adhesive	5/22/2002	STARD	FDPEP
Hearing Devices			
▶ MED-EL COMBI 40+ Cochlear Implant System	8/20/2001	STARD	FDPEP
▶ Nucleus 24 Auditory Brainstem Implant System	10/20/2000	STARD	FDPEP
▶ SOUNDTEC Direct Drive Hearing System	9/7/2001	STARD	FDPEP
▶ Vibrant Soundbridge	8/31/2000	STARD	FDPEP
Heart			
▶ AMPLATZER Septal Occluder	12/5/2001	STARD	FDPEP
▶ ATS Open Pivot Bileaflet Heart Valve	10/13/2000	STARD	FDPEP
▶ Cordis Checkmate System	11/3/2000	STARD	FDPEP
▶ Edwards Prima Plus Stentless Bioprosthesis Model 2500P	2/27/2001	STARD	FDPEP
▶ NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	6/15/2000	STARD	FDPEP
▶ Novoste Beta-Cath System	11/3/2000	STARD	FDPEP
▶ On-X Prosthetic Heart Valve	5/30/2001	STARD	FDPEP
▶ Phylax AV Implantable Cardioverter Defibrillator with Program Software	9/29/2000	STARD	FDPEP
▶ QuickSeal Arterial Closure System	3/25/2002	STARD	FDPEP
Heart Devices			
▶ AMPLATZER PFO Occluder	4/5/2002	STARD	FDPEP
▶ AMPLATZER Septal Occluder	12/5/2001	STARD	FDPEP
▶ ATS Open Pivot Bileaflet Heart Valve	10/13/2000	STARD	FDPEP
▶ Cordis Checkmate System	11/3/2000	STARD	FDPEP
▶ Edwards Prima Plus Stentless Bioprosthesis Model 2500P	2/27/2001	STARD	FDPEP
▶ NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	6/15/2000	STARD	FDPEP
▶ Novoste Beta-Cath System	11/3/2000	STARD	FDPEP
▶ On-X Prosthetic Heart Valve	5/30/2001	STARD	FDPEP
▶ Phylax AV Implantable Cardioverter Defibrillator with Program Software	9/29/2000	STARD	FDPEP
▶ QuickSeal Arterial Closure System	3/25/2002	STARD	FDPEP
Heart Valve			
▶ ATS Open Pivot Bileaflet Heart Valve	10/13/2000	STARD	FDPEP
▶ Edwards Prima Plus Stentless Bioprosthesis Model 2500P	2/27/2001	STARD	FDPEP
▶ Mosaic Porcine Bioprosthesis, Model 305 (Aortic) and Model 310 (Mitral)	7/14/2000	STARD	FDPEP
▶ On-X Prosthetic Heart Valve	5/30/2001	STARD	FDPEP
Hemostat			
▶ CoStasis/DynaStat Surgical Hemostat	6/13/2000	STARD	FDPEP
Hepatitis			
▶ AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	7/5/2001	STARD	FDPEP

▶ COBAS AMPLICOR Hepatitis C Virus (HCV) Test, version 2.0 (v2.0)	7/3/2001	TEXT	PDF
▶ Devices for Testing the Hepatitis B Virus (HBV)	3/30/2001	TEXT	PDF
▶ Elecsys Anti-HBs Immunoassay and Elecsys PreciControl Anti-HBs	2/27/2002	TEXT	PDF
▶ Elecsys HBsAg Immunoassay, Elecsys HBsAg Confirmatory, and PreciControl HBsAg	6/1/2001	TEXT	PDF
▶ IMMULITE HBsAg and IMMULITE 2000 HBsAg and Confirmatory Kit	7/26/2002	TEXT	
▶ IMMULITE ₃ Anti-HBc and IMMULITE ₃ 2000 Anti-HBc	7/24/2002	TEXT	
▶ IMMULITE ₃ Anti-HBc IgM and IMMULITE ₃ 2000 Anti-HBc IgM	7/26/2002	TEXT	
▶ IMMULITE ₃ Anti-HBs and IMMULITE ₃ 2000 Anti-HBs	7/22/2002	TEXT	
▶ Vitros Immunodiagnostic Products Anti-HCV Reagent Pack and Calibrator	8/30/2001	TEXT	PDF
▶ Vitros Immunodiagnostic Products HBsAg Reagent Pack and Calibrator, and HBsAg Confirmatory Kit	4/27/2001	TEXT	PDF
Hip Prostheses			
▶ PROSTALAC Hip Temporary Prosthesis	3/23/2001	TEXT	PDF
Hypodermic Needles			
▶ Q-103 Needle Management System	12/21/2000	TEXT	PDF
In Vitro Diagnostics (IVD)			
▶ N Latex Cystatin C Test Kit	3/13/2001	TEXT	PDF
▶ PATHWAY [®] Her 2 (Clone CB11)	11/28/2000	TEXT	PDF
▶ Vitros Immunodiagnostic Products Anti-HBs Reagent Pack and Calibrators	9/29/2000	TEXT	PDF
Incontinence			
▶ AMS Sphincter 800 Urinary Prosthesis	6/14/2001	TEXT	PDF
Infusion			
▶ Medtronic IsoMed Constant Flow Infusion System	7/21/2000	TEXT	PDF
Infusion Pumps			
▶ Medtronic IsoMed Constant Flow Infusion System	7/21/2000	TEXT	PDF
Intraocular Lens (IOL)			
▶ CeeOn Edge Foldable Ultraviolet Light-Absorbing Posterior Chamber Intraocular Lens - Model 911A	4/5/2001	TEXT	PDF
Jaw Surgery			
▶ TMJ Fossa Eminence Prosthesis	2/27/2001	TEXT	PDF
Lap-Band			
▶ LAP-Band ₃ Adjustable Gastric Banding (LAGB ₃) System	6/5/2001	TEXT	PDF
Lasers			
▶ Diomed 630 PDT Laser Model T2USA	6/30/2000	TEXT	PDF
▶ Hyperion LTK System	6/30/2000	TEXT	PDF
▶ ViewPoint CK System	4/11/2002	TEXT	PDF


Lithotripters

▶ Medstone STS Lithotripter 9/5/2000  

Lung Cancer

▶ RapidScreen RS-2000 7/12/2001  

Mammography



▶ MammoReader 1/15/2002  


▶ SenoScan Full Field Digital Mammography System 9/25/2001  

Microwaves

▶ TMx-2000 BPH Thermotherapy System 6/29/2001  

Monitors

▶ Corometrics 120 F-Series Maternal/Fetal Monitor with Integrated Fetal Oxygen Saturation Monitoring 2/9/2001  

▶ OxiFirst Fetal Oxygen Saturation Monitoring System 5/12/2000  

Needles

▶ Disintegrator Insulin Needle Destruction Unit 3/15/2002  

▶ Q-103 Needle Management System 12/21/2000  

Ob/Gyn

▶ Gynecare Intergel Adhesion Prevention Solution 11/16/2001  

Ob/Gyn Surgical Devices



▶ Gynecare Intergel Adhesion Prevention Solution 11/16/2001  

Obesity

▶ LAP-Band[®] Adjustable Gastric Banding (LAGB[®]) System 6/5/2001  


Occlusion Devices

▶ AMPLATZER[®] PFO Occluder 4/5/2002  

▶ TRUFILL[®] n-Butyl Cyanoacrylate (n-BCA) Liquid Embolic System 9/25/2000  


Orthopedic

▶ AFFINITY[®] Cage System 6/13/2002  

▶ Ascension MCP 11/19/2001  

▶ BAK/Cervical (BAK/C) Interbody Fusion System 4/20/2001  

▶ OssaTron 10/12/2000  

▶ UBIS 5000 Ultrasound Bone Sonometer 7/17/2001  

Oxygen

▶ OxiFirst Fetal Oxygen Saturation Monitoring System 5/12/2000  

Pacemaker

▶ Home Monitoring System with the BA03 DDDR Pulse Generator 10/11/2001  








▶ Integrity AFx DR Model 5346	7/11/2001	STX	PDR
▶ Medtronic InSync Biventricular Pacing System including the InSync Model 8040 Pulse Generator, Attain LV Model 2187 and Attain CS Model 2188 Leads	8/28/2001	STX	PDR
▶ Microny SR+ Cardiac Pacemaker (Model 245T)	12/21/2000	STX	PDR
Pacing Systems			
▶ Home Monitoring System with the BA03 DDDR Pulse Generator	10/11/2001	STX	PDR
▶ Integrity AFx DR Model 5346	7/11/2001	STX	PDR
▶ Medtronic InSync Biventricular Pacing System including the InSync Model 8040 Pulse Generator, Attain LV Model 2187 and Attain CS Model 2188 Leads	8/28/2001	STX	PDR
▶ Microny SR+ Cardiac Pacemaker (Model 245T)	12/21/2000	STX	PDR
Parkinson's Disease			
▶ Activa3 Parkinson's Control System	1/14/2002	STX	PDR
Penile Devices			
▶ Mentor Alpha I Inflation Penile Prosthesis	7/14/2000	STX	PDR
Prostate			
▶ AMS Sphincter 800-Urinary Prosthesis	6/14/2001	STX	PDR
▶ Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay - P990055	9/8/2000	STX	PDR
▶ Diagnostic Products Corporation Total Prostate Specific Antigen (PSA) Assays on the Immulite and Immulite 2000 Analyzers	6/19/2001	STX	PDR
▶ Dimension RxL PSA Flex Reagent Cartridge	7/5/2001	STX	PDR
▶ Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	12/12/2000	STX	PDR
▶ Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	11/22/2000	STX	PDR
▶ TMx-2000 BPH Thermotherapy System	6/29/2001	STX	PDR
Prostate Cancer			
▶ Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	12/12/2000	STX	PDR
▶ Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	11/22/2000	STX	PDR
Prostate Surgery			
▶ AMS Sphincter 800-Urinary Prosthesis	6/14/2001	STX	PDR
Prostheses			
▶ Avanta Metacarpophalangeal (MCP) Joint Implant Finger Prosthesis	8/28/2001	STX	PDR
PSA			
▶ Bayer Immuno 1 Complexed Prostate-Specific Antigen (PSA) Assay - P990055	9/8/2000	STX	PDR
▶ Dimension RxL PSA Flex Reagent Cartridge	7/5/2001	STX	PDR
▶ Roche Elecsys free Prostate-Specific Antigen (fPSA) Assay on the Elecsys 1010 and 2010 immunoassay analyzers	12/12/2000	STX	PDR
▶ Roche Elecsys Total Prostate-Specific Antigen (PSA) Assay on the 1010 and 2010 immunoassay analyzers	11/22/2000	STX	PDR

Pumps			
▶	Medtronic IsoMed Constant Flow Infusion System	7/21/2000	TEXT PDF
Radioactive Spheres			
▶	SIR-Spheres	3/5/2002	TEXT PDF
Radiofrequency Ablation			
▶	NAVI-STAR Diagnostic/Ablation Deflectable Tip Catheter	6/15/2000	TEXT PDF
▶	Stocker 70 RF Generator	5/31/2000	TEXT PDF
Restenosis			
▶	Cordis Checkmate System	11/3/2000	TEXT PDF
▶	Novoste Beta-Cath System	11/3/2000	TEXT PDF
Sealants			
▶	CoSeal™ Surgical Sealant	12/14/2001	TEXT PDF
▶	FocalSeal-Synthetic Absorbable Sealant	5/28/2000	TEXT PDF
▶	QuickSeal Arterial Closure System	3/25/2002	TEXT PDF
▶	Vascular Solutions Duett Sealing Device	6/22/2000	TEXT PDF
Septal Occluders			
▶	AMPLATZER PFO Occluder	4/5/2002	TEXT PDF
▶	NNMT Medical, Inc. CardioSEAL Septal Occlusion System with QwikLoad	12/5/2001	TEXT PDF
Sharps			
▶	Disintegrator Insulin Needle Destruction Unit	3/15/2002	TEXT PDF
▶	Q-103 Needle Management System	12/21/2000	TEXT PDF
Shock Wave Therapy			
▶	Dornier Epos Ultra	1/15/2002	TEXT PDF
▶	OssaTron	10/12/2000	TEXT PDF
▶	Siemens SONOCUR Basic	7/19/2002	TEXT
Skin			
▶	Composite Cultured Skin (CCS)	2/21/2001	TEXT PDF
▶	DERMAGRAFT	9/28/2001	TEXT PDF
▶	INTEGRA Dermal Regeneration Template	4/19/2002	TEXT
Skin Grafts			
▶	Composite Cultured Skin (CCS)	2/21/2001	TEXT PDF
Skin Substitutes			
▶	DERMAGRAFT	9/28/2001	TEXT PDF
Sodium Hyaluronate			
▶	STAARVISC Sodium Hyaluronate	4/18/2001	TEXT PDF
▶	SUPARTZ Dispo	1/24/2001	TEXT PDF

Spinal Fusion

- ▶ BAK/Cervical (BAK/C) Interbody Fusion System 4/20/2001  
- ▶ InFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device 7/2/2002  

Stents

- ▶ BeStent® 2 with Discrete Technology® Over-The-Wire and Rapid Exchange Coronary Stent Delivery Systems 10/18/2000  
- ▶ BiodivYsio AS PC (phosphorylcholine) Coated Stent Delivery System 9/29/2000  
- ▶ IntraCoil® Self-Expanding Peripheral Stent 4/3/2002  
- ▶ Neuroform® Microdelivery Stent System 9/11/2002 

Stimulator

- ▶ Activa® Parkinson's Control System 1/14/2002  
- ▶ Genesis Neurostimulation (IPG) System 11/21/2001  
- ▶ Nucleus 24 Auditory Brainstem Implant System 10/20/2000  

Stomach Band

- ▶ LAP-Band® Adjustable Gastric Banding (LAGB®) System 6/5/2001  

Temporomandibular Joint

- ▶ TMJ Fossa Eminence Prosthesis 2/27/2001  

Temporomandibular Joint (TMJ) Implants

- ▶ TMJ (Temporomandibular Joint) Metal-on-Metal Total Joint Replacement Prosthesis System 1/5/2001  
- ▶ TMJ Fossa Eminence Prosthesis 2/27/2001  

Test Kits

- ▶ Psychomedics Corporation Opiate Assay 12/11/2000  

Testicular Prosthesis

- ▶ Mentor Saline-Filled Testicular Prosthesis 7/19/2002  

Tuberculosis

- ▶ QuantiFERON®-TB 11/28/2001  

Ultrasound

- ▶ UBIS 5000 Ultrasound Bone Sonometer 7/17/2001  

Urology

- ▶ Deflux® Injectable Gel 9/24/2001  

Ventilators

- ▶ Model 3100B High-Frequency Oscillatory Ventilator 9/24/2001  

Vesicoureteral Reflux

- ▶ Deflux® Injectable Gel 9/24/2001  

Wart Removal

▶ Wartner Wart Removal System 2/20/2002 [TEXT](#) [PDF](#)

Weight Loss Devices

▶ LAP-Band Adjustable Gastric Banding (LAGB) System 6/5/2001 [TEXT](#) [PDF](#)

Women's Health

▶ Lea's Shield 3/14/2002 [TEXT](#) [PDF](#)

Wound and Burn Dressing

▶ OrCel Bilayered Cellular Matrix 8/31/2001 [TEXT](#) [PDF](#)

Wound Healing Devices

▶ Composite Cultured Skin (CCS) 2/21/2001 [TEXT](#) [PDF](#)

▶ DERMAGRAFT 9/28/2001 [TEXT](#) [PDF](#)

X-Rays

▶ RapidScreen RS-2000 7/12/2001 [TEXT](#) [PDF](#)

2. 検索の事例

(1) Nuroform Microdelivery Stent System – H020002 (資料(3)-2-(1)-1)

下記の概要が表示される。

FDA は本件機器を HDE プログラムに基づき承認した。以下の安全性と予想される利点の概要 (SSPB) のへのリンク、ならびに本件製品、その使用される適応症 (indication)、および FDA 承認の根拠についての更に完全な情報についてはその他のサイトを参照のこと。

(<http://www.fda.gov/cdrh/ode/hdeinfo.html>) これは HDE へのリンク先

製品名：

メーカー：

承認日：

承認通知書：

どんな製品か？：

どのように作動するのか？：

どのような時に使用するのか？：

どのような目的を達成するのか？：

どのような時に使用してはいけないのか？：

追加情報：

この後、詳細をクリックすると先に説明をしたパート1からその他までのページが出てくる。(資料(3)-2-(1)-2)

第一部 - 承認書

第二部 - 安全性と予想される利点の概要 [Word]

第三部 - 表示

その他の一般情報

パート1をクリックすると

CDRHからの認証時の文書がPDFで現れる。これは改ざん防止もあると思われる。承認書そのもののファイルである。(資料(3)-2-(1)-3)

次にパート2をクリックすると、

Neuroform™ Microdelivery Stent System – H020002 (資料(3)-2-(1)-4)

安全性と予想される利点の概要 (SSPB)

- I. 一般的情報
- II. 使用される適応症
- III. 禁忌
- IV. 警告および使用上の注意
- V. 機器の説明 (description)
- VI. 選択方法と手段
- VII. 市販履歴
- VIII. 健康に対する有害効果
- IX. 臨床前の試験の概要
- X. 臨床情報の概要
- XI. リスク／予想される利点の分析
- XII. 委員会の勧告
- XIII. CDRH の決定
- XIV. 承認の明細
- XV. 引例

という順番で、詳細な情報が記載されている。

次にパート3をクリックすると、

Neuroform™ Microdelivery Stent Sytem (資料(3)-2-(1)-5)

使用説明

注意

機器の説明

使用上の注意

禁忌

警告

の説明がされている。

この、研究書には、これら特定機器の内容説明は行わないが、その基本となる項目のみを取り上げた。

HDE へのリンクをすると下記のような説明がされている。(資料(3)-2-(1)-6)

人に使用する機器

一般情報

1996年6月26日付で、FDAは、人に使用する機器（HUD）に関する1990年の安全な医療機器法の条項を実施するための最終的な規則を公布しました。この規則は、1996年10月24日付で施行されています。HUDは、米国で年間4,000人に満たない人達に影響する疾病または健康状態を治療や診断することで患者に利益を与えるためのものです。疾病や健康状態が影響を与える患者の人口が少ない場合、機器のメーカーの開発研究費は、市場からの収益を越えてしまいます。そこで、FDAは、患者人口の少ない疾病の治療や診断に使用する機器の開発を奨励するために、本規則を作成し公布しました。

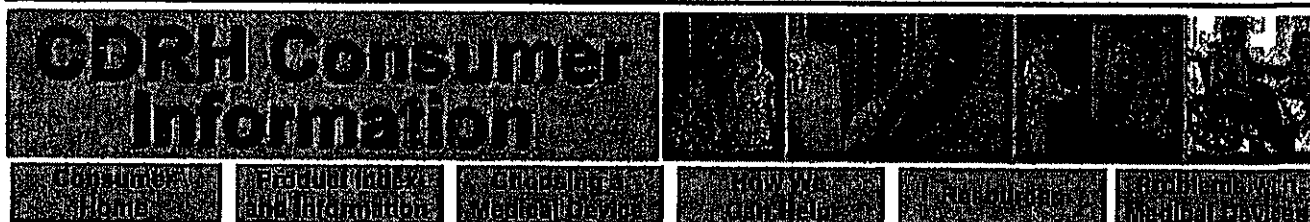
規則では、人に使用する機器の免除（HDE）申請の提出を定めています。この申請は、フォームと内容が市販前（PMA）申請と同一ですが、PMAの有効性の要件が免除されます。HDE申請には、機器がその意図する目的に有効である旨を証明する科学的に有効な臨床研究の結果を入れる義務はありません。ただし、申請には、現在使用できる機器や代替りの治療方法を考慮して機器が不当または重大な疾患や傷害のリスクを生じないこと、および予想される健康への利点が当該機器の使用による疾患や傷害のリスクを上回ることを、FDAが判断するのに十分な情報が入っていないなければなりません。さらに、申請は、類似の機器がいずれも疾病や健康状態の治療または診断に使用できないことを証明しなければなりません。

承認されたHDEは、HUDの販売を許可しています。ただし、HUDは、FDAの承認した適応症に機器を使用することに対してIRB承認が得られた後にのみ使うことができます。HUDの表示には、その機器が人に使う機器であること、および機器が連邦法で認められてはいても、特定の適応症についての機器の有効性は証明されていないことを記さなければなりません。

資料(3)-2-(1)-1

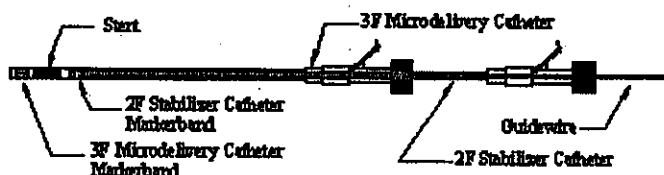
Neuroform™ Microdelivery Stent System – H020002
の概要

原文（英文）とその和訳



New Humanitarian Device Approval

Neuroform™ Microdelivery Stent System - H020002



FDA approved this device under the Humanitarian Device Exemption (HDE) program <http://www.fda.gov/cdrh/ode/hdeinfo.html>. See the links below to the Summary of Safety and Probable Benefit (SSPB) and other sites for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Neuroform™ Microdelivery Stent System
Manufacturer: SMART Therapeutics, Inc.
Address: 2551 Merced Street, San Leandro, California 94577
Approval Date: September 11, 2002
Approval Letter: <http://www.fda.gov/cdrh/pdf2/h020002a.pdf>

What is it? The Neuroform™ Microdelivery Stent System is designed to prevent the rupture of an aneurysm in the brain (an intracranial aneurysm). An aneurysm is formed by an abnormally weakened area in an artery wall. As time passes, the weak area stretches to form a balloon-like bulge in the artery wall. Without treatment, the weakened area could rupture and hemorrhage.

For a drawing of a cerebral aneurysm go to:
<http://www.nlm.nih.gov/medlineplus/ency/imagepage/17031.htm>

For a drawing of an intracranial aneurysm go to:
<http://www.nlm.nih.gov/medlineplus/ency/imagepage/8615.htm>

The device consists of a stent and a delivery system. The stent is a small wire mesh in the shape of a tube that is permanently placed at the opening (neck) of the aneurysm. The delivery system consists of flexible tubes (catheters) used to carry the stent to the aneurysm for placement.

How does it work? The delivery system carries and delivers the stent to the aneurysm site. The stent is placed across the neck of the aneurysm. When the stent expands in place to conform to the inside of the artery wall, the delivery catheter is withdrawn. The physician then passes another catheter through one of the small openings in the mesh of the stent and slides small metal coils (called embolic coils) through this second catheter into the aneurysm. The coils block blood from going into the aneurysm to help prevent the aneurysm from rupturing, and the stent keeps the coils from falling out of the aneurysm sac.

When is it used? The Neuroform™ Microdelivery Stent System is for use with embolic coils for the treatment of wide neck intracranial aneurysms that cannot be treated by placing a metal clip around the aneurysm neck (surgical clipping).

What will it accomplish? The stent provides a barrier to hold the embolic coils within the aneurysm. The coils cause clotting that helps to block blood from going into the aneurysm and may help to keep it from rupturing.

When should it not be used? On patients who cannot take blood-thinning (antiplatelet and/or anticoagulation) drugs that help prevent blood-clotting.

Additional information: SSPB and Labeling: <http://www.fda.gov/cdrh/ode/h020002sum.html>

Other

National Institutes of Health:

- Aneurysm sites; causes; symptoms; therapy; prevention:
<http://www.nlm.nih.gov/medlineplus/ency/article/001122.htm#visualFile>
- Cerebral aneurysm: http://www.ninds.nih.gov/health_and_medical/disorder_index.htm

Cleveland Clinic: Drawing of aneurysm; information on brain & abdominal aneurysms

- <http://www.clevelandclinic.org/health/health-info/docs/0300/0391.asp?index=3930>

Mayo Clinic: Drawing of aneurysm with stent; information on aneurysms

- <http://www.mayoclinic.com/invoke.cfm?id=DS00017>

Updated 10/11/02

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Neuroform™ Microdelivery Stent System – H020002

FDA は本件機器を HDE プログラム (<http://www.fda.gov/cdrh/ode/hdeinfo.html>) に基づき承認した。以下の安全性と予想される利点の概要 (SSPB) のへのリンク、ならびに本件製品、その使用される適応症 (indication)、および FDA 承認の根拠についての更に完全な情報についてはその他のサイトを参照のこと。

製品名 : Neuroform™ Microdelivery Stent System

メーカー : SMART Therapeutics, Inc.

住所 : 2551 Merced Street, San Leandro, California 94577

承認日 : 2002 年 9 月 11 日

承認通知書 : <http://www.fda.gov/cdrh/pdf2/h020002a.pdf>

どのような製品か? : Neuroform™ Microdelivery Stent System は脳内の動脈瘤 (頭蓋内動脈瘤) の破裂を予防するために設計されている。動脈瘤は動脈壁の異常に弱い領域で形成される。経時的に、弱い領域は伸展し動脈壁に気球状の拡張部を形成する。

脳動脈瘤の図については以下へ :

<http://www.nlm.nih.gov/medlineplus/ency/imagepage/17031.htm>

頭蓋内動脈瘤の図については以下へ :

<http://www.nlm.nih.gov/medlineplus/ency/imagepage/8615.htm>

この機器はステントとデリバリー・システムにて構成されている。ステントは管状の小さな金網で動脈瘤の開口部 (付け根(neck)) に常時留置される。デリバリー・システムは、ステントを動脈瘤に留置するために使用する弾性のある管(カテーテル)から成っている。

どのように作動するのか? : デリバリー・システムはステントを運び動脈瘤部位に到達させる。このステントは動脈瘤の付け根に横たえて留置する。ステントが動脈壁の内側に沿って適切に拡張したら、デリバリー・カテーテルを引く。医師はもう一つのカテーテルをステントの網の小さな開口部に通し、小さな金属コイル (塞栓コイルと称する) をこの二番目のカテーテルを通して動脈瘤に滑り込ませる。コイルは動脈瘤に血液が流入するのを妨げ、動脈瘤の破裂を予防し、ステントはコイルが動脈瘤囊から落下するのを防止する。

いつ使用するのか? : Neuroform™ Microdelivery Stent System は、動脈瘤の付け根にメタルクリップ (外科的クリップ) を留置する処置が行えない、付け根の大きい頭蓋内動脈瘤の治療用に塞栓コイルと共に用いるためのものである。

どのような目的を達成するのか？：このステントは動脈瘤内に塞栓コイルを保持するためのバリアを提供する。コイルは、動脈瘤内に血液が入り込むのを防ぐのに役立つ動脈瘤の破裂を防ぐのに役立つ血液凝固を引き起こす。

いつ使用してはいけないのか？：血液凝固を防ぐのに有効な血液抗凝固（抗血小板物質および／または抗凝固薬）薬剤を服用できない患者。

追加情報：SSPB とラベル表示：<http://www.fda.gov/cdrh/ode/h020002sum.html>

その他

国立保健研究所（National Institutes of Health）：

・動脈瘤サイト；原因；症状；治療；予防：

<http://www.nlm.nih.gov/medlineplus/ency/article/001122.htm#visualFile>

・脳動脈瘤：http://www.ninds.nih.gov/health_and_medical/disorder_index.htm

クリーブランド・クリニック：動脈瘤の図；脳および腹部動脈瘤に関する情報

・<http://www.clevelandclinic.org/health/health-info/docs/0300/0391.asp?index=3930>

メイヨ・クリニック：ステントのある動脈瘤の図；動脈瘤に関する情報

・<http://www.mayoclinic.com/invoke.cfm?id=DS00017>

10/11/02 更新

資料(3)-2-(1)-2

**Neuroform Microdelivery Stent System – H020002
の詳細（構成）**

原文（英文）とその和訳

Neuroform Microdelivery Stent System -- H020002

Issued September 11, 2002

- [Part 1 - Approval Order](#)
- [Part 2 - Summary of Safety and Probable Benefit \[Word\]](#)
- [Part 3 - Patient Labeling](#)
- [Other Consumer Information](#)

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Updated 10/11/2002