Work Sheet

1. **Is the SUD an implant as defined in 21 CFR Part 860.3(d)?**

   Yes or NO

   If the answer to question #1 above is Yes, STOP. SUD is categorized as High Risk.

2. **What is the risk of infection according to Flowchart 1?**

   Low Risk or Moderate Risk or High Risk

   If the answer to question #2 is High Risk, STOP. SUD is categorized as High Risk.

3. **What is the risk of inadequate performance according to Flowchart 2?**

   Low Risk or Moderate Risk or High Risk

   If the answer to question #3 is High Risk, STOP. SUD is categorized as High Risk.

4. **Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.**

5. **Did the SUD result in a Low Risk on Flowcharts 1 AND 2? If so, the SUD is low risk.**

Please circle appropriate risk categorization below.

Low Risk or Moderate Risk or High Risk

Appendix 2

List of Frequently Reprocessed SUDs

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Cardiovascular	Angiography catheter	870.1200	N	510(k)	II	DQO	high
	blood pressure cuff	870.1120	N	510(k)	II	DXQ	low
	cardiac ablation catheter	unclassified	N	PMA	III	LPB	high
	cardiac guidewire	870.1330	N	510(k)	II	DQX	high
	compressible limb sleeve	870.5800	N	510(k)	II	JOW	low
	Electrophysiology recording catheter	870.1120	N	510(k)	II	DRF	high
	intra aortic balloon catheter	870.3535	N	510(k)	III	DSP	high
	needle	870.1390	N	510(k)	II	DRC	high
	percutaneous transluminal coronary angioplasty (PTCA) catheter	unclassified	N	PMA	III	LOX	high
	percutaneous transluminal angioplasty (PTA) catheter	unclassified	N	510(k)	II	LIT	high
	syringes	870.1670, 870.1650, unclassified	N	510(k)	II	DXT	high
	trocar	870.1390	N	510(k)	II	DRC	moderate
Respiratory	breathing mouthpiece	868.5620	Y	N/A	I	BYP	low
	endotracheal tubes	unclassified	N	PMA	III	LZN	high
	masks	868.5550	Y	N/A	I	BSJ	low
	oral and nasal catheters	868.5350	Y	N/A	I	BZB	low
	respiratory therapy and anesthesia breathing circuits	868.5240	Y	N/A	I	CAI	moderate
	tracheobronchial suction catheter	868.6810	N	510(k)	I	BSY	high

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Gastroenterology/ Urology	biliary sphincterotomes	876.4300	N	510(k)	II	KNS	high
	biopsy needles	876.1075	N	510(k)	II	FCG	high
	endoscopic guidewires	876.1500	N	510(k)	II	KOG	low
	endoscopic staplers	876.4400	N	510(k)	II	FHN	low
	extraction balloons/baskets	876.1500	N	510(k)	II	KOG	high
	non-electric biopsy forceps	876.1075	N	510(k)	II	FCL	high
	trocar	876.5090	N	510(k)	II	FBQ	low
	urethral catheters	876.5130	N	510(k)	II	KOD	moderate
Nephrology	hemodialysis blood tubing	876.5820	N	510(k)	II	KOC	moderate
OB-GYN	laparoscopic dissectors	884.1720	Y	N/A	I	HET	low
	laparoscopic graspers	884.1720	Y	N/A	I	HET	high
	laparoscopic scissors	8884.1720	Y	N/A	I	HET	high
	trocar	884.1720	N	510(k)	II	HET	low
Orthopedics	arthroscopy instruments	888.1100	N	510(k)	II	HRX	low
	carpal tunnel blade	888.4540	Y	N/A	I	LXH	moderate
	drill bits	878.4540	Y	N/A	I	HTW	low
	external fixation device	878.3900, 878.3910	Y	N/A	I	FZF, FYH	low
	flexible reamers/drills	886.4070 878.4820	Y	N/A	I	GEY, HRG	low
	saw blades	878.4820	Y	N/A	I	GFA, DWH, GEY, GET	low
	surgical drills	878.4820	Y	N/A	I	GEY, GET	low
Surgery	biopsy forceps	876.1075 876.4300 884.4530 874.4680 874.4680	N	510(k)	II	FCL KGE HFB BWH JKK	high
	biopsy needles	878.4800	Y	N/A	I	DWE	high
	burr	878.4820	Y	N/A	I	GFF, GEY	low

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
	electrosurgical electrodes/handles/ pencils	876.4300 878.4800	N	510(k)	II	HAM, GEI, FAS, FEH, KNS	moderate
	endoscopes	876.1500	N	510(k)	II	many	high
	endoscopic blades	876.1500	N	510(k)	II	GCP, GCR	moderate
	endoscopic guidewires	876.1500	N	510(k)	II	GCP, GCR	low
	enodoscopic staplers	888.4540	Y	N/A	I	HXJ	moderate
	fascia holders	878.4800	Y	N/A	I		moderate
	laproscope	884.1720 876.1500	N	510(k)	II	HET, GCJ	low
	laser fiber delivery systems	878.4810 874.4500 874.4770 874.4496 878.4810 886.4390 884.4550 886.4690	N	510(k)	II	GEX, EWG, LXR, LMS, LLW, HQF, HHR, HQB,	low
	scissor tips, removable inserts	878.4800 888.4540 884.4520 874.4420	Y	N/A	I	LRW, HHR, HDK, HDJ, JZB, KBD	moderate
	surgical cutting accessories	878.4800 874.4420	Y	N/A	I	GDZ, GDX, GES, KBQ, KAS	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	Y	N/A	I	KAB KBG KCI	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	N	510(k)	II	FBQ, FBM, GCJ, DRC	moderate

Medical Specialty/Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Plastic Surgery	stapler	878.4800 882.4190	Y	N/A	I	GAG, GEF, FHM, HBT, HBS	moderate
Laboratory	glucometer lancets	878.4800	Y	N/A	I	FMK	low
Ophthalmic	keratome blade	886.4370	N	510(k)	I	HMY, HNO, MYD	high
	OR drapes	878.4370	N	510(k)	II	KKX	moderate
	phacoemulsification needle	886.4670	N	510(k)	II	MUS	high
Infection Control	OR gowns	878.4040	N	510(k)	II	FYA	low
	sharps containers	880.5570	N	510(k)	II	MTV, FMI	low
	syringes, piston	880.5860	N	510(k)	II	FMF	high
General Hospital	infusion pump, implanted	unclassified	N	PMA	III	MDY, LKK	high
	syringe, irrigating	880.6960	Y	N/A	I	KYZ, KYY	low
Dental	braces, plastic	872.5470	N	510(k)	II	DYW	high
	braces, metal	872.5410	Y	N/A	I	EJF	high
	burr	872.3240	Y	N/A	I	EJL	moderate

NOTE: Appendix A of this guidance has been superseded by Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data Attachment 1. List of SUDS Known to be Reprocessed or Considered for Reprocessing.

NOTE: Some enforcement dates in this document have been extended as explained in the FDA Talk Paper of August 16, 2001, available at http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01098.html. For additional information about the enforcement extensions, see Letter to Hospitals (September 25, 2001), available at http://www.fda.gov/cdrh/reuse/reuse-letter-092501.html.

Guidance for Industry and for FDA Staff

Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

Document issued on: August 14, 2000

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Enforcement III
Office of Compliance

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to, Larry D. Spears, HFZ-340, 2098 Gaither Road, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Larry D. Spears at 301-594-4646 or by electronic mail at lxs@cdrh.fda.gov.

Additional Copies

Additional copies are available from the World Wide Web/CDRH home page: http://www.fda.gov/cdrh/reuse/index.shtml or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1168 when prompted for the document shelf number.

Contents

Guidance[1] on Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

Abstract

The "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" document provides guidance to third party and hospital reprocessors about their responsibility as manufacturers engaged in reprocessing devices labeled for single use under the Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997. Third party and hospital reprocessors of single-use devices are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements (Sections 513 and 515 of the Act; 21 Code of Federal Regulations Parts 807 and 814).

[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Background

On November 3, 1999, FDA released a proposed strategy on the reuse of single-use devices (SUDs)[2]. This proposal identified the steps under consideration in the development of the agency's SUD reprocessing policy. These steps were:

1. develop a list of commonly reprocessed SUDs;
2. develop a list of factors to determine the degree of risk associated with reprocessing devices;
3. apply those factors to the list of commonly reprocessed SUDs and categorize them into three categories – high, moderate, and low; and
4. develop priorities for the enforcement of premarket submission requirements for third party and hospital reprocessors based on the category of risk.

In addition to publishing the proposed strategy document for public comment, FDA also sponsored a teleconference on November 10, 1999, and convened an open public meeting on December 14, 1999[3], to obtain comments on the proposed strategy. As a result of the comments we received, FDA published on February 11, 2000, two companion draft guidances entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" ("RPS guidance")[4] and "Enforcement Priorities for

[2] 64 FR 59782-59783, Nov. 3, 1999.
[3] 64 FR 63818-63819, Nov. 22, 1999.
[4] 65 FR 7027-7029, Feb. 11, 2000.

Single-Use Devices Reprocessed by Third Parties and Hospitals" ("SUD Enforcement guidance")[5].

Summary of the proposed RPS guidance:

The draft guidance "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" set forth factors that the agency would consider in categorizing the risk associated with SUDs that are reprocessed. This process, called the Risk Prioritization Scheme, would determine the risk categories for frequently reprocessed SUDs by assigning an overall risk to each SUD based on the risk of infection and the risk of inadequate performance following reprocessing. The three categories of risk were high, moderate, and low. The risk category would then be used to set FDA's enforcement priorities for premarket submission requirements. Appendix 2 of the RPS guidance included a list of frequently reprocessed SUDs and their risk category according to the Risk Prioritization Scheme. Under this proposed guidance document, FDA would consider any reprocessed SUD that was not included on the list to be high risk.

Summary of the proposed SUD Enforcement guidance:

The draft guidance "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" set forth FDA's priorities for enforcing premarket submission requirements for premarket notifications (510(k)) or for premarket approval

[5] Id.

applications (PMA) based on the risk categorization of a device as determined by the companion RPS guidance. Premarket submission requirements for SUDs deemed high risk by the Risk Prioritization Scheme would be actively enforced within six (6) months of the issuance of FDA's final guidance document on reuse; within twelve (12) months for moderate risk SUDs; and within eighteen (18) months for low risk SUDs. FDA would enforce third party and hospital reprocessors non-premarket requirements (e.g., registration, listing, medical device reporting, tracking, corrections and removals, quality system, and labeling) within six (6) months of issuance of FDA's final reuse guidance document.

Summary of major comments received by FDA:

FDA received over 150 written comments to the Docket on the November 1999 proposed strategy plan and to the February 2000 draft guidances. A copy of the comments may be obtained from the Dockets Management Branch, HFA-305, Food and Drug Administration, 5600 Fishers Lane, Room 1061, Rockville, MD 20857.

The following is a summary of the major comments received:

- Strong support for the agency's decision to actively regulate third party and hospital reprocessors.
- Concern that the Risk Prioritization Scheme lacked clarity and was too subjective. To demonstrate this point, several stakeholders used the scheme to

evaluate their products. In all cases the stakeholders' risk category for their devices ranked higher or lower than FDA's risk category for the same devices.

- Concern that FDA was imposing burdensome regulations on hospitals.
- Concern that many hospitals are not prepared to comply with the agency's premarket requirements due to their lack of experience in this area or to their limited financial resources.
- Support for FDA's decision to exclude "opened-but-unused" SUDs from this enforcement strategy. The agency will further examine its policy with respect to "opened-but-unused" products. In the meantime, FDA's current policy for "opened-but-unused" products remains unchanged.
- Several stakeholders identified additional SUDs that they were currently reprocessing or were considering reprocessing in the future that were not on FDA's current list of frequently reprocessed SUDs.

Major changes to FDA's proposed reuse strategy:

As a result of the comments the agency received, FDA has revised the final SUD regulatory strategy as follows:

1. The proposed Risk Prioritization Scheme will not be used to determine the timing of FDA's enforcement priorities for the premarket requirements. Rather, FDA will use the device classification listed in the Code of Federal Regulations

(CFR) (i.e., class I, class II, or class III) to set its enforcement priorities for the premarket submission requirements.

2. FDA intends to enforce premarket submission requirements within six (6) months of issuance of this final SUD Enforcement guidance document for all class III devices; within twelve (12) months for class II devices; and eighteen (18) months for class I devices. At a later date, FDA intends to examine on a case-by-case basis, the need to revoke exemptions from premarket requirements for class I and II exempt products based upon the risks that may exist due to reprocessing.

3. For hospital reprocessors, FDA intends to establish a one (1) year phase in for active enforcement of the Act's non-premarket requirements (e.g., registration, listing, medical device reporting, tracking, corrections and removals, quality system, labeling). The agency will use the one-year period following the issuance of this final guidance document to educate hospitals about their regulatory obligations. FDA does not anticipate that the one-year extension of enforcement discretion following the issuance of this guidance document will pose any significant public health risks because the agency has no evidence at this time to demonstrate that reprocessing and reuse of SUDs is posing any imminent danger to public health.

4. The "List of Frequently Reprocessed SUDs" has been expanded to include additional SUDs that are currently being reprocessed. As noted above, FDA will use the device classification listed in the CFR to set its enforcement priorities for the premarket submission requirements for all devices. The regulatory premarket submission requirements for reprocessed SUDs that are not included on this list will be based on the device's CFR classification (e.g., class I, II, or III).

As stated in FDA's November 3, 1999, proposed strategy plan on the reuse of single-use devices, our primary goal is to ensure a reprocessing and reuse regulatory program based on good science that protects public health, while ensuring that our regulatory requirements are equitable to all parties. FDA does not believe that the changes to its final SUD regulatory strategy pose any significant public health risks. Rather, we believe that these changes may facilitate the implementation of the reuse policy. For example, FDA believes that using the existing CFR device classification system may reduce the chance for delaying implementation of the final SUD policy by eliminating confusion or misunderstanding regarding a device's risk category and the timing of premarket submissions.

The major change in FDA's plan is the use of the traditional device classification scheme rather than the draft Risk Prioritization Scheme to establish enforcement priorities for the premarket submission requirements. FDA was concerned about significant differences between the risk category assigned to a SUD by FDA and by

stakeholders. Subjective differences in interpreting the Risk Prioritization Scheme could cause some SUD reprocessors to believe that their devices are a lower risk category than FDA's assessment. The agency concluded that disagreements over the agency's risk category for a SUD could cause undue delays in reprocessors complying with the Act's premarket submission requirements. The existing CFR device classification system, on the other hand, is an established categorization system that is familiar to all device manufacturers and many device users. Using the CFR device classification system would eliminate problems with the proposed Risk Prioritization Scheme identified by stakeholders.

We greatly appreciate the many comments, suggestions for improvement, and encouragement we received from our stakeholders and interested parties in response to the proposed strategy plan and to the two draft guidance documents. We carefully considered all comments and have incorporated many comments into the final guidance document.

We encourage continued feedback as we proceed with this initiative.

Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals[6]

A. Introduction

This guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" ("SUD Enforcement guidance") finalizes FDA's policy on how it intends to regulate third party and hospital reprocessors engaged in reprocessing single-use devices (SUDs) for reuse. This guidance document incorporates many comments and suggestions received from stakeholders and interested parties in response to "FDA's Proposed Strategy on the Reuse of Single-Use Devices" (published on November 4, 1999); comments from FDA's satellite teleconference entitled "FDA's Proposed Strategy on Reuse of Single-Use Medical Devices" (held on November 8, 1999); comments from the FDA Open Public Meeting (held on December 14, 1999); the two companion draft guidances entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (published on February 11, 2000); and the numerous meetings the agency has held with stakeholders and interested parties.

This SUD enforcement guidance document sets forth FDA's priorities for enforcing premarket submission requirements, based on the device's Code of Federal Regulations

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