Preamendments Class III Strategy (Text Only)

MEMORANDUM

Date: April 19, 1994

From: Acting Director, Office of Device Evaluation

Subject: Preamendments Class III Strategy

To: ODE Division Directors

I. Purpose

This document provides a strategy for implementation of Safe Medical Devices Act of 1990 mandated activities for preamendments Class III devices.

II. Background

The 1976 amendments did not immediately subject preamendments devices classified in class III to the premarket approval process. The Act requires FDA to publish 515(b) regulations directing the submission of premarket approval applications for preamendments class III devices. The 515(b) process involves the publication of two Federal Register notices, the Proposed Rule and the Final Rule. The 515(b) Proposed Rule announces FDA's intention to call for PMAs, lists the issues to be addressed in PMA submissions, states a deadline for the receipt of comments, and affords an opportunity to request reclassification. The Final Rule addresses any comments received, repeats the issues to be addressed in PMA submissions, and sets a deadline for the submission of Premarket Approval Applications (PMA) or Investigational Device Exemptions (IDE) of not more than 90 days after the date of publication. At that time, any manufacturer with neither PMA nor IDE must cease distribution of the device. The 1976 Act did not allow a 515(b) regulation to require submission of a PMA for a device until 30 months after the device is classified in class III, or 90 days after the 515(b) regulation is published, whichever is later. Since the last classification regulations were published in 1987, the thirty month period has elapsed for all preamendments Class III devices.

The Safe Medical Device Act of 1990's (SMDA's) new section 515(i) requires FDA to order industry submission of a summary of and a citation to any information known or otherwise available to the manufacturer, including

adverse safety and effectiveness information, for preamendments class III devices not yet subject to a 515(b) final order and to reconsider their classification in light of redefinition of class II. The Safe Medical Devices Act of 1990 (SMDA) revised the definition of class II to include devices for which "general controls" by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish "special controls", rather than to establish "performance standards" as had been required by the 1976 Act. SMDA also directs FDA to revise the classification of such preamendments class III devices into class I or class II or require the device to remain in class III; and directs FDA to issue a schedule for 515(b) rulemaking within 12 months of publication of a regulation retaining a device in class III. However SMDA does not prevent the FDA from proceeding immediately to section 515(b) rulemaking on specific devices, in the interest of public health, independent of the 515(i) process.

ODE Division Directors Page

In light of these SMDA provisions and FDA resources, the 117 preamendments class III devices on which FDA has not initiated any action have been grouped as follows:

Group 3 includes 42 devices that are not presently considered candidates for reclassification. FDA believes these devices are in commercial distribution and will require submission of PMAs in the near future.

Group 2 includes 31 devices that the FDA believes have a high potential for reclassification into class II.

Group 1 includes 44 devices which have fallen into disuse or limited use. FDA believes that rulemaking under section 515(b) of the act will be unlikely to result in viable PMAs or reclassification petitions.

III. Procedure

The grouping and prioritization of preamendments class III devices facilitates the following achievable SMDA activities by December 1, 1995, listed in the order of endeavor:

A: High Priority Group 3Devices

CDRH will initiate 515(b) rulemaking for fifteen high priority Group 3 devices over the next three years according to the schedule presented in Appendix A.

High priority Group 3 devices are those determined currently to present a unreasonably high risk to public health because significant issues of safety and/or effectiveness are not being resolved or, to the best of FDA's knowledge, have little probability of being resolved. The schedule indicates the year of publication of the section 515(b) proposed rule for a device. The timetable for publication of each final rule will have to be based upon specific data needs, comments received, and the existence (if any) of reclassification petitions to be reviewed. These devices are not presently considered candidates for reclassification. The high priority preamendments class III list and schedule is presented in Appendix A.

B. Remaining Group 3 Devices

CDRH will also issue, in 1994, a section 515(i) order for the remaining twenty-seven Group 3 devices and pursue the same course of evaluation and prioritization described below in section C. The prioritization will result in a schedule determined by the information received. Although these remaining Group 3 devices are not presently considered candidates for reclassification, FDA's evaluation of the data submitted in responseto the 515(i) order will include an assessment of whether one or more of these devices should be moved to Group 2. The continued marketing of the remaining Group 3 devices pending this evaluation does not present as great a risk to the public health in the light of FDA's current knowledge and experience with the devices. The remaining Group 3 devices are listed in Appendix B.

C. Group 2 Devices

CDRH will issue, in 1994, a section 515(i) order requiring manufacturers to submit all safety and effectiveness information available or known to them including adverse information for all Group 2 devices. All thirty-one Group 2 devices are considered strong candidates for reclassification. Group 2 includes devices for which existing questions of safety and/or effectiveness that have been or can be answered by information already obtained or being obtained by manufacturers. SMDA modified the definition of Class II devices, as noted above, to rely upon "special controls" to provide reasonable assurance of safety and effectiveness. "Special controls" are defined by SMDA to include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions, known as 510(k)s), recommendations, and other appropriate actions. The SMDA modified definition of Class II together with increased experience with the device may provide grounds for reclassification.The schedule for Group 2 devices is listed in Appendix C.

CDRH will complete review and evaluation of the safety and effectiveness information obtained under the 515(i) order. Assignment of devices into groups and prioritization for 515(b) rulemaking will be revised accordingly. CDRH will then proceed with rulemaking to reclassify devices or retain them in class III and revising the schedule of section 515(b) rulemaking for those devices retained in class III.

D. Group 1 Devices

CDRH will propose section 515(b) rulemaking in 1994 for a group of forty-four devices which have fallen into disuse, designated as group 1. Group 1 includes devices that raise significant questions of safety and/or effectiveness but are rarely in current use. All forty-four devices will be included in the same 515(b) proposed rule document. Group 1 devices are listed in Appendix D.

E. Devices from Prior Federal Register Priority Lists

CDRH will complete 515(b) rulemaking and the review of reclassification petitions and PMAs for the devices identified as high priority devices in the Uline_beginFederalUline_end Uline_beginRegisterUline_end of September 6, 1983 (48/FR/40272) and the Uline_beginFederalUline_end Uline_beginRegisterUline_end of January 6, 1989 (54/FR/550) which have not been reevaluated and placed in one of the three groups. Two devices listed in the 1983 notice have been grouped into Group 3. Ten devices listed in the 1989 FR notice are now included in Group 1, seven are in Group 3, and eight are in Group 2. The Final Rule (preceded by a proposed rule) has been published and 20 PMAs have been received for 8 of the devices listed in both FR notices. Nine additional proposed rules have been published resulting in seven reclassification petitions. Two of the listed devices have been reclassified. See Appendix E.

Susan Alpert, M.D., Ph.D.

APPENDIX A: High Priority Group 3 Devices

1994

872.3540	OTC denture cushion or pad
872.3570	OTC denture repair kit
872.6730	Endodontic dry heat sterilizer
876.5280	Implanted mechanical/hydraulic urinary contingence device
888.3320	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis
888.3330	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prothesis

	890.5290	Shortwave diathermy
1995		
	872.3600	Partially fabricated denture kit
	888.3410	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis
	890.5275	Microwave diathermy
1996		
	888.3150	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis
	888.3650	Shoulder joint metal/polymer non-constrained cemented prosthesis
	890.5300	Ultrasonic diathermy
	890.5525	Iontophoresis device
	890.5860	Ultrasound and muscle stimulator

Appendix B: Remaining Group 3 Devices

868.2450	Lung Water Monitor
868.2500	Cutaneous Oxygen Monitor
868.5610	Membrane Lung for long term pulmonary support
870.1025	Arrythmia detector and alarm
870.3300	Arterial embolization device

870.3375	Cardiovascular intravascular filter
870.3450	Vascular graft prosthesis of less than 6mm diameter
870.3535	Intra-aortic Balloon and Control System
870.3600	External Pacemaker Pulse Generator
870.3610	Implantable Pacemaker Pulse Generator
870.3700	Pacemaker programmers
870.3800	Annoloplasty Ring
870.4230	Cardiopulmonary Bypass Defoamer
870.5225	External Counter-Pulsating Device
870.5550	External Transcutaneous Cardiac Pacemaker (noninvasive)
874.3400	Tinnitus Masker
874.3930	Tympanostomy Tube with Semi-Permeable Membrane
874.5350	Suction Antichoke Device
874.5370	Tongs Antichoke Device
876.5870	Sorbent Hemoperfusion system
876.5955	Peritoneo-venous Shunt
882.1790	Ocular Plethysmograph
882.5860	Implanted neuromuscular stimulator
882.5950	Artificial embolization device
884.5940	Powered Muscle Vaginal Stimulator for Therapeutic Use

886.3400	Keratoprosthesis
890.3890	Stair Climbing Wheelchair

APPENDIX C: Group 2

1995

864.7250	Erythropoietin Assay
864.7300	Fibrin Monomer Paracoagulation Test
876.3630	Penile Rigidity Implant
878.5360	Tweezer-type Epilator
884.1060	Endometrial Aspirator
884.1100	Endometrial Brush
884.1185	Endometrial Washer
886.3920	Eye Valve Implants

1996

866.3305	Herpes Simplex Virus Serological Reagents
866.3510	Rubella Virus Serological Reagents
870.3620	Pacemaker Lead Adaptor
872.6080	Airbrush
876.4480	Electrohydraulic Lithotriptor
878.3610	Esophageal Prosthesis

	878.3720	Tracheal Prosthesis
	884.4100	Endoscopic Electrocautery and Accessories
	884.4150	Bipolar Endoscopic Coagulator-Cutter and Accessories
1997		
	868.1150	Indwelling Blood Carbon Dioxide Partial Pressure Analyzer
	868.1170	Indwelling Blood Hydrogen Ion Concentration Analyzer
	868.1200	Indwelling Blood Oxygen Partial Pressure Analyzer
	870.3680	Cardiovascular Permanent Pacemaker Electrodes
	870.4260	Cardiopulmonary Bypass Arterial Line Blood Filter
	870.4350	Cardiopulmonary Bypass Oxygenator
	876.5860	High Permeability Hemodialysis system
	878.5650	Topical O2 Chamber
	882.5940	Electroconvulsive Therapy Device
	888.3660	Shoulder Semi-constrained
1998		
	870.3710	Pacemaker Repair or Replacement Material
	870.4320	Cardiopulmonary Bypass Pulsatile Flow Generator
	870.5200	External Cardiac Compressor

876.5540	Implanted Blood Access Device

APPENDIX D: Group 1 Devices

864.5220	Automated differential cell counter (intended for uses other than to flag or identify specimens containing abnormal blood cells)
868.5400	Electroanesthesia apparatus
870.1350	Catheter balloon repair kit
870.1360	Trace microsphere
870.3850	Carotid sinus nerve stimulator
870.3545	Ventricular bypass (assist) device
870.5300	High energy DC-defibrillator (including paddles)
872.3400	Karaya and 12% or more sodium borate with and without acacia denture adhesive
872.3420	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive
872.3480	Polyacrylamide polymer (modified cationic) denture adhesive
872.3500	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive
872.3560	OTC denture reliner
872.3820	Root canal filling resin if chloroform is used as an ingredient in the device

876.5220	Colonic irrigation system for uses other than colon cleansing when medically indicated such as before radiological or endoscopic examinations
876.5270	Implanted electrical urinary continence device
880.5760	Chemical cold pack snakebite kit
882.1825	Rheoencephalograph
882.5150	Intravascular occluding catheter
882.5850	Implanted spinal cord stimulator for bladder evacuation
884.2050	Obstetric data analyzer
884.2620	Fetal electroencephalographic monitor
884.2685	Fetal scalp clip electrode and applicator
884.4250	Expandable cervical dilator
884.4270	Vibratory cervical dilator
884.5050	Metreurynter-balloon abortion system
884.5225	Abdominal decompression chamber
888.3120	Ankle joint metal/polymer non-constrained cemented prothesis
888.3180	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis
888.3200	Finger joint metal/metal constrained uncemented prosthesis
888.3210	Finger joint metal/metal constrained cemented

	prothesis
888.3220	Finger joint metal/polymer constrained cemented prosthesis
888.3300	Hip joint metal constrained cemented or uncemented prosthesis
888.3310	Hip joint metal/polymer constrained cemented or uncemented prosthesis
888.3370	Hip joint (hemi-hip) acetabular metal cemented prosthesis
888.3380	Hip joint femoral (hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis
888.3480	Knee joint femorotibial metallic constrained cemented prosthesis
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
888.3550	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis
888.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis
888.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis
888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis
888.3680	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis
888.3790	Wrist joint metal constrained cemented prosthesis
890.3610	Rigid pneumatic structure orthosis

APPENDIX E: Status of devices listed in the Federal Register of September 6, 1983 (48/FR/40272) and the Federal Register of January 6, 1989 (54/FR/550).

Devices listed in 48/FR/40272

CFR	Name of Device	Status	PMAs Received, Approved
864.5220	Automated Differential Cell Counter	Reclassified 06/8/90	
864.5680	Automated Heparin Analyzer	Reclassified 10/4/93	
864.9245	Automated Blood Cell Separator (CBER Review)	515(b) Prop. 02/19/88	
870.3925	Replacement Heart Valve	515(b) Final (5/13/87)	5 R,4 A
870.3610	Implantable Pacemaker Pulse Generator	Reevaluated, Group 3	
870.3700	Pacemaker Programmer	Reevaluated, Group 3	
880.5130	Infant Radiant Warmer	515(b) Prop. (1/15/86) Reclassification Pet.	Pending
882.5840	Implanted Intracerebral/ Subcortical Stimulator for Pain Relief	515(b) Final (3/01/89)	2 R,2 W
882.5820	Implanted Cerebellar Stimulator	515(b) Final (6/28/84)	0 R
882.5830	Implanted Diaphragmatic/Phrenic Nerve Stimulator	515(b) Final (4/08/86)	1 R,1 A
884.1600	Transabdominal Amnioscope (Fetoscope) and Accessories	515(b) Final (1/29/87)	0 R

884.5360	Contraceptive Intrauterine Device (IUD) and Introducer	515(b) Final (8/04/86)	0 R
884.5380	Contraceptive Tubal Occlusion Device and Introducer	515(b) Final (12/31/87	2 R,1 A

Devices listed in 54/FR/550

CFR	Device	Status	PMAs Received Approved
866.3305	Herpes Simplex Virus Serological Reagents	Group 2	
866.3510	Rubella Virus Serological Reagents	Group 2	
868.5400	Electroanesthesia apparatus	Group 1	
868.5610	Membrane lung for long-term pulmonary support	Group 3	
870.3450	Vascular graft prostheses of less than 6 millimeters diameter	Group 3	
870.3535	Intra-aortic balloon and control system	Group 3	
872.3640	Endosseous implant	515(b) Prop.(12/7/89) Reclassification Pet.	Pending
872.6730	Endodontic dry heat sterilizer	High Priority Group 3	
874.3850	Endolymphatic Shunt Tube with valve	515(b) Prop.(05/4/90) Reclassification Pet.	Pending
876.3750	Testicular Prosthesis	515(b) Prop.(01/8/93)	

876.4480	Electrohydraulic lithotriptor	Group 2		
878.3530	Silicone Inflatable Breast Implants	515(b) Prop.(01/8/93)		
878.3540	Silicone gel-filled Breast Prosthesis	515(b) Final (7/9/91)	10	R
880.5760	Chemical cold pack snakebite kit	Group 1		
882.5800	Cranial electrotherapy stimulator	515(b) Prop. (3/31/93) Reclassification Pets.		Pending
884.1185	Endometrial Washer	Group 2		
884.4100	Endoscopic Electrocautery and accessories	Group 2		
884.5940	Powered Muscle Vaginal Stimulator for Therapeutic Use	Group 2		
886.3400	Keratoprosthesis	Group 3		

CFR	Device	Status	PMAs Received	Approved
886.3920	Eye valve implant	Group 2		
888.3480	Knee joint femorotibial metallic constrained cemented prosthesis	Group 1		
888.3540	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	Group 1		
888.3550	Knee joint patellofemorotibial	Group 1		

	polymer/metal/metal constrained cemented prosthesis	
888.3570	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	Group 1
888.3580	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	Group 1
888.3640	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	Group 1
888.3650	Shoulder joint metal/polymer semi-constrained cemented prosthesis	High Priority Group 3
888.3660	Shoulder joint metal/polymer semi-constrained cemented prosthesis	Group 2
888.3680	Shoulder joint glenoid (hemi-shoulder) metallic cemented prosthesis	Group 1
890.3610	Rigid pneumatic structure orthosis	Group 1
890.3890	Stair-climbing wheelchair	Group 3

Not identified in Federal Register Notice of Intent

CFR	Device	Status	PMAs
870.4360	Nonroller-type Cardiopulmonary Bypass Blood Pump	515(b) Prop. (7/06/93) Reclassification Pet.	Pending

876.3350	Penile Inflatable Implant	515(b)	Prop. (4/28/93)	Pending

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)