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JUN 30 1993

Proposal for Establishing  
Mechanisms for Setting Review  
Priorities Using Risk Assessment and  
Allocating Review Resources

**PROPOSAL FOR ESTABLISHING MECHANISMS FOR SETTING REVIEW  
PRIORITIES USING RISK ASSESSMENT AND ALLOCATING  
REVIEW RESOURCES**

**ISSUE**

It is important to ensure that proper time, attention, and scientific expertise is given to all PMA, 510(k), and IDE applications. Because devices vary in their complexity and risk, the level of effort in evaluation should be appropriate for each type of device, so as to maximize utilization of CDRH resources in the protection of the public health. To this end, we must assess incoming submissions to ensure that sufficient resources are dedicated to the review of high risk Class III devices and that resources are conserved in the review of low risk Class I devices.

**DISCUSSION OF PROGRAM**

The Office of Device Evaluation (ODE) reviews approximately 11,000 regulatory submissions per year. This figure represents the sum of all premarket notifications [510(k)s], premarket approval applications (PMAs), and Investigational Device Exemptions (IDEs), including their supplements.

The devices that are the subject of these submissions range from the simplest Class I devices such as dental chair and accessories to the most sophisticated Class III devices such as Excimer Lasers used in ophthalmology for refractive surgery. Furthermore, individual submissions within a submission type vary in review difficulty depending upon the scientific issues presented and the quality of the particular document.

Each submission type represents a regulatory finding that is unique to that type of submission. For example, when a device is cleared through a 510(k) submission, it has been determined that the device is substantially equivalent to a Preamendment Class I, II or Class III device. Premarket approval represents the highest level of regulatory control that the agency can apply to devices and requires that the applicant provide reasonable assurance of the safety and effectiveness of the device. The basic criteria for approval of an IDE are that the risk to human subjects who participate in the research study is reasonable and that the experimental design will give useful data.

Given the finite number of resources that the Center has available and the requirement to make sound scientific/regulatory decisions in a timely manner, it is critical that the Center have procedures in place to ensure the proper allocation of resources in the review process to optimize the overall protection that can be provided for public health.

There are several policies in place that utilize various methods to facilitate the review process. For example, Blue Book Memo 191-1 which applies to PMAs, 510(k)s, and IDEs identifies the principles and procedures to be followed in the "sequencing and review of major documents submitted to ODE." This memo defines the policy of "First-In-First-Reviewed" (FIFR) and establishes the review priorities among the types of submissions. There are also various manuals, guidelines, checklists and flow charts explaining the review process for all types of submissions.

The regulatory timeframes for submissions have established a de facto order for review, namely that IDEs have the shortest regulatory review clock (30 days) followed by 510(k)s (90 days), and then PMAs (180 days). Because ODE receives IDEs, 510(k)s, and PMAs, each of which compete for available resources, the "First-In-First-Reviewed" policy gives guidance to the review staff on the Office review priorities. While implemented to address criticism made by an Office of the Inspector General (OIG) audit team about the Office's ability to provide equity to all submitters of applications, it directly relates to the overall concept of prioritization. This policy established a baseline prioritization for the review of all submissions within each submission type.

The Center intends to implement additional policies addressing this issue in a more focused way and to develop mechanisms to ensure that appropriate resources are assigned to the review of marketing applications.

## ANALYSIS

To assess the proportion of regulatory submissions for devices posing the need for a relatively low priority decision, we have produced a report of the total number of 510(k) submissions for fiscal years 1987 through 1992, identified the number of submissions by Class, and rated the submission by priority score using a range of 1 through 100; with 1 being devices with the lowest level of risk and 100 being devices possessing a very high potential for clinical risk.

The data indicate there were 6245 Class I 510(k)s submitted during this period which constituted 28% of all submissions. There were 15,758 510(k)s for devices with a device priority model score of less than 30 submitted during this time, representing 71% of the total 510(k) submissions. The volume of applications identified underscores the need for having streamlined mechanisms in place to evaluate applications for low priority devices. Different review procedures could reduce the time spent on a large proportion of these applications per year.

The current 510(k) documentation form establishes that the simplest of 510(k)s will undergo the least scientific scrutiny, while the devices with new technology or different performance

characteristics when compared to a predicate device are subject to the most rigorous equivalence evaluation. However, because 510(k)s represent the largest number of regulatory submissions, reallocation of resources used in the review of 510(k)s could yield the most impact by freeing resources to concentrate on higher priority items.

Class I devices, by definition, are those devices whose safety and effectiveness can be assured through minimal regulation. Approximately 40% of Class I devices have been exempt from the Premarket Notification requirements by regulation. Exemption means that no formal submission or notification needs to be filed with the FDA prior to introduction of the device into commercial distribution. The exemption from the need to file a submission does not exempt the manufacturer from other regulatory requirements. The criteria for exemption were established in the early 1980's and were applied until the last exemption became effective in 1989. Because the evaluation of devices under 510(k) is a dynamic process, it may prove beneficial to periodically evaluate Class I devices for additional exemptions as well as to revisit the exemption criteria in light of 1993 standards.

While many devices have been exempted by regulation, the remaining Class I devices still subject to 510(k) could be subjected to a less rigorous scientific evaluation without adversely affecting the public health. If these devices were the subject of a limited evaluation, the chances of making an error resulting in a compromise of the public health would be remote. Because manufacturers of Class I devices often make unfounded claims for their devices or promote them for intended new uses, an evaluation process that concentrates on a device's indication use would contribute significantly to the prevention of marketing unsafe or ineffective devices.

The relatively short timeframe surrounding the review of IDEs (a 30 calendar day review period) makes the impact of these new procedures difficult to evaluate when measured by review time. The 30 day statutory timeframe for review mandates an efficient identification of needed expertise and a timely completion of review. The only IDEs that routinely require FDA review are IDE's for devices which pose significant risk to study subjects. Such devices often involve new technology and/or new intended uses. Their review generally requires considerable expertise. The need for such expertise will undoubtedly increase in the future as CDRH undertakes a more rigorous involvement in clinical study design.

PMA's are required for devices utilizing new technologies or otherwise requiring a detailed assessment of safety and effectiveness. The PMA process is the most involved review process that CDRH undertakes in the evaluation of medical devices. In this regard, ODE has consistently attempted to streamline review procedures when such streamlining did not represent a significant compromise of public protection. If the incoming PMA submission meets criteria previously established by the Safe Medical Devices Act of 1990 to streamline the process, it will not be routinely reviewed by an Advisory Panel or the Biometrics staff in the Office of Surveillance and Biometrics.

We could more effectively utilize available resources if (1) the review needs of each

application were determined early in the process, (2) information on available expertise elsewhere within CDRH were provided, (3) resources outside ODE were available for participation in the premarket review program, and (4) these shared resources were trained in review requirements and authorities.

#### ADDITIONAL CONSIDERATIONS AND RELATED PLANS

One way to better utilize available resources is to identify incomplete or grossly inadequate submissions quickly upon receipt in the agency. The mechanisms for accomplishing this are being addressed separately under the Refuse to File Policies. If submissions that do not merit scientific review are identified early in the process, Center resources will be conserved. In addition, the Expedited Review Policy, which provides for the placement of applications with potentially significant public health benefit at the front of the review queue, will work in conjunction with the Refuse to File Policy and priority setting/resource allocation to further focus utilization of review resources.

#### RECOMMENDATIONS

As a means to ensure an optimum use of review resources, the following recommendations are made:

1. Establish a three tier system of review to accommodate different priority levels for devices. In order to be effective, the system must be flexible to permit the reassignment of applications among the tiers based upon inherent risk, but not so flexible as to allow higher tier reassignments without just cause.

Tier III - Intensive scientific and labeling review, using a team review approach, for all first and second of a kind devices utilizing new technology or having new intended use(s), as well as other PMAs and 510(k)s determined by their inherent risk to require an intensive review. Advisory panel input is highly recommended for this tier of devices.

Tier II - Routine scientific and labeling review for the majority of 510(k)s and select PMAs.

Tier I - Essentially a focused labeling review for intended use/indications for use.

2. Educate ODE employees on the new procedures to ensure consistency and understanding.
3. Reallocate ODE human resources to maximize utilization of existing personnel in the review of devices with major public health impact i.e., temporarily reassign reviewers and branch chiefs to the busiest, most demanding, public health areas. These temporary reassignments should be advertised so that those responding to the need are

aware of its import to the Center and commended for their commitment to the good of the organization.

4. Provide a means to identify and utilize resources from other areas within CDRH to assist in the implementation and achievement of the plans and goals identified in this document.
5. Revise Blue Book Memo I91-1 ("First-In-First-Reviewed") to optimize the number of IDE, PMA and 510(k) decisions made in a consistent manner. The priority for 510(k) and PMA review must be adjusted to ensure parity on the basis of public health need.
6. Formulate strategy to implement the "four of a kind" provision of SMDA which will allow FDA to use the data from the first four PMAs of a particular device to support reclassification or other regulatory reforms.
7. Revisit and, if necessary, revise the criteria used to exempt low risk devices from 510(k) regulation.
8. Identify device related voluntary performance standards for which conformance insures a measure of safety and effectiveness. Develop a self-certification statement for manufacturers of low-risk devices to provide that their device conforms with applicable voluntary performance standards. Randomly perform audits to ensure compliance.

## CONCURRENCE

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# TALK PAPER

FOOD AND DRUG ADMINISTRATION  
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T93-28  
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## DEVICE "FAST TRACK" PLAN ANNOUNCED

FDA is receiving inquiries about media stories on its new plan to give "fast track" review to potentially life-saving medical devices.

The following can be used to answer questions.

The agency has developed a plan designed to speed up review of critical medical devices while, at the same time, ensuring that these products get the close scrutiny necessary to assure their safety and effectiveness. The goal of the plan is to get promising new medical devices to the public as quickly as is reasonably possible.

The new plan has four elements: expedited review, risk assessment of new products, status reports to manufacturers, and refusal to file incomplete or inadequate applications.

\* **Expedited Review:** Devices that represent a major advance in medical care will be put on a "fast track" separate from all others. Included in this category will be most life-saving devices and those that appear to offer decidedly greater clinical benefits or lower risks than existing products.

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\* Risk Assessment: FDA will determine the potential health risks presented by each device and will focus its resources on devices that present the greatest potential risk. The higher the risk, the more rigorous the level of scientific scrutiny the device will receive.

\* Status Reports to Manufacturers: The agency has established a computerized system to enable manufacturers to ascertain within three days the status of their pre-market notification submission for a new device. Firms will be informed about the position of their submissions in the review queue, and the expected review time.

\* Refusal-to-file Policy: In order to more effectively utilize the agency's scientific resources available for the evaluation of medical devices, FDA will refuse to file applications that are not reasonably complete and worthy of scientific assessment. Upon receipt, each application will be given a preliminary review. If the minimum criteria for filing specified in the statute and the regulations are not met, the application will not be accepted. This policy will enable the agency to devote its resources to applications that are ready for review.

The new strategy for reviewing applications will be announced Wednesday, June 30, before a meeting of the advisory panel chairpersons of the Medical Devices Advisory Committee. The meeting will be held at 1:30 p.m. at the Holiday Inn Crown Plaza, Rockville, Md.

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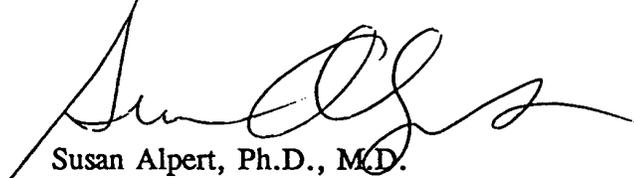


## Memorandum

Date JAN 27 1994  
From Acting Director, ODE (HFZ-400)  
Subject DOD Tier Categorizations (Triage Lists)  
To Director, CDRH (HFZ-1)

Attached please find the Tier Categorizations for devices regulated by the Division of Ophthalmic Devices (DOD). The attached list is an integrated divisional list that includes devices for the Ophthalmic Devices Panel. It reflects implementation of the primary recommendation proposed in the Triage Management Action Plan "Proposal for Establishing Mechanisms for Setting Review Priorities Using Risk Assessment and Allocating Review Resources". The categorizations were reviewed by the chairman of the Ophthalmic Devices Panel and his comments were considered in development of this list.

DOD has implemented use of the tier system in the review of incoming documents. The list has also been forwarded to DSMA for inclusion in the electronic public docket.



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

Attachment

## DIVISION OF OPHTHALMIC DEVICES PRODUCTS FOR TRIAGE

### Tier I Products

#### Class I products:

E	886.1040	Ocular esthesiometer
AC	886.1050	Adaptometer
AC	886.1070	Anomaloscope
AC	886.1090	Haidinger brush
E,AC	886.1140	Ophthalmic chair
E	886.1150	Visual acuity chart
AC	886.1160	Color vision plate illuminator
E	886.1170	Color vision tester
E	886.1190	Distometer
E	886.1200	Optokinetic drum
AC	886.1250	Euthyscope
E	886.1270	Exophthalmometer
AC	886.1290	Fixation device
E	886.1320	Fornixscope
E	886.1330	Amsler grid
AC	886.1340	Haploscope
AC	886.1350	Keratoscope
E	886.1375	Bagolini lens
E	886.1380	Diagnostic condensing lens
E	886.1390	Flexible diagnostic Fresnel lens
E	886.1395	Diagnostic Hruby fundus lens
E	886.1400	Maddox lens
E	886.1410	Ophthalmic trial lens clip
E	886.1415	Ophthalmic trial lens frame
E	886.1420	Ophthalmic lens gauge
AC	886.1425	Lens measuring instrument
AC	886.1430	Ophthalmic contact lens radius measuring device
AC	886.1435	Maxwell spot
AC	886.1450	Corneal radius measuring device
E	886.1460	Stereopsis measuring instrument
E	886.1500	Headband mirror
E,AC	886.1605	Perimeter
E	886.1650	Ophthalmic bar prism
E	886.1655	Ophthalmic Fresnel prism
E	886.1660	Gonioscopic prism Note: 886.1385 in Tier II
E	886.1665	Ophthalmic rotary prism
AC	886.1680	Ophthalmic projector
AC	886.1690	Pupillograph
E,AC	886.1700	Pupillometer
E	886.1770	Manual refractor
E	886.1780	Retinoscope, battery operated
E	886.1790	Nearpoint ruler
E	886.1800	Schirmer strip
E,AC	886.1810	Tangent screen (campimeter)
E	886.1840	Simulatan
E	886.1860	Ophthalmic instrument stand
E,AC	886.1870	Stereoscope
E	886.1880	Fusion and stereoscopic target
E	886.1905	Nystagmus tape
E,AC	886.1910	Spectacle dissociation test system
NE	886.1945	Transilluminator, battery powered
E	886.4230	Ophthalmic knife test drum
NE	886.4250	Ophthalmic electrolysis unit, battery powered
NE	886.4335	Operating headlamp, battery operated
E,C	886.4350	Manual ophthalmic surgical instrument

Tier I Products - continued

E,C	886.4360	Ocular surgery irrigation device
AC	886.4370	Keratome
E	886.4445	Permanent magnet
E,C	886.4570	Ophthalmic surgical marker
NE	886.4750	Ophthalmic eye shield (corneal shields must be Tier II)
E	886.4770	Ophthalmic operating spectacles (loupes)
E,AC	886.4855	Ophthalmic instrument table
E	886.5120	Low-power binocular loupe
E	886.5420	Contact lens inserter/remover
E	886.5540	Low-vision magnifier
E	886.5600	Ptosis crutch
E	886.5800	Ophthalmic bar reader
E	886.5810	Ophthalmic prism reader
AC	886.5820	Closed-circuit television reading system
E,C	886.5840	Magnifying spectacles
NE	886.5842	Spectacle frame
E,C	886.5844	Prescription spectacle lens
NE	886.5850	Sunglasses (nonprescription) - concerns about excessive claims will persist until this product is exempted from 510(k).
E	886.5870	Low-vision telescope
NE	886.5900	Electronic vision aid
E	886.5910	Image intensification vision aid
E,AC	886.5915	Optical vision aid

Class II products:

AC,S	886.1120	Ophthalmic camera
AC,M	886.1220	Corneal electrode
AC,S	886.1300	Afterimage flasher
AC,S	886.1360	Visual field laser instrument *Must not exceed FDA accessible emission limits for Class I lasers (CFR 21 Part 1040.10).
---	886.1405	Ophthalmic trial lens set
AC,D	886.1510	Eye movement monitor Usually neurology device (882.1460) because of labeling and indications for use.
AC,S	886.1570	Ophthalmoscope
AC,S	886.1630	AC-powered photostimulator CONCERN ABOUT UNSUBSTANTIATED CLAIMS?
AC	886.1640	Ophthalmic preamplifier
---	886.1750	Skiascopic rack
AC,S	886.1760	Ophthalmic refractometer
AC	886.1780	Retinoscope, AC
AC,S	886.1850	AC-powered slitlamp biomicroscope
AC	886.1945	Transilluminator, A.C. powered
AC	886.4250	Ophthalmic electrolysis unit, A.C. powered
AC	886.4335	Operating headlamp, AC operated
AC	886.4400	Electronic metal locator
AC	886.4440	AC-powered magnet
86-LXQ		Eye Cup

## Tier II Products

### Class I products:

NE	886.4070	Powered corneal burr
NE,P	886.4300	Intraocular lens guide (includes folders and injectors)

### Class II products:

M,ST	886.1385	PMMA diagnostic contact lens
--	886.1670	Ophthalmic isotope uptake probe
S	886.1930	Tonometer and accessories Subtypes may go to Tier I.
ST	886.1940	Tonometer sterilizer, CERTIFICATION ONLY
M	886.3100	Ophthalmic tantalum clip
M	886.3130	Ophthalmic conformer
M	886.3200	Artificial eye
M	886.3300	Absorbable implant (scleral buckling method)
M	886.3320	Eye sphere implant
M	886.3340	Extraocular orbital implant
M	886.3800	Scleral shell
S	886.4100	Radiofrequency electrosurgical cautery apparatus
S	886.4115	Thermal cautery unit
--	886.4150	Vitreous aspiration and cutting instrument
--	886.4170	Cryoophthalmic unit
*	886.4390	Ophthalmic laser
*	886.4392	Nd:YAG laser for posterior capsulotomy (other surgical procedures Tier III)
--	886.4610	Ocular pressure applicator
--	886.4670	Phacofragmentation system
--	886.4690	Ophthalmic photocoagulator
M	886.4790	Ophthalmic sponge
--	886.5100	Ophthalmic beta radiation source
--	86-LRX	Contact Lens Cases
--	86-HPX	PMMA Contact Lenses
--	---	Hard (PMMA) Contact Lens Solutions

### Class III products:

--	886.3400	Keratoprosthesis
*	886.3600	Intraocular lens (Standard Materials & Design)
*	886.3920	Eye valve implant
*	886.4270	Intraocular gas
*	886.4275	Intraocular fluid
*	886.5918	Rigid gas permeable contact lens solution
*	886.5928	Soft (hydrophilic) contact lens solution
*	886.5925	Soft (hydrophilic) contact lens (standard materials, designs, and intended uses)
	886.5933	Contact lens heat disinfection unit
*	886.5916	Rigid gas permeable contact lens (standard materials, designs, and intended uses)
*	86-LOG	Balloon Catheter for Retinal Reattachment
--	86-LOH	Contact Lens Identification System
--	86-LYX	Corneal Storage Media
--	86-LQJ	Laser Surgical Lens
--	86-LQB	Medical Computers and Software for Ophthalmic Use
*	86-LOI	Neodymium:YAG Ophthalmic Laser for Uses Other Than Posterior Capsulotomy & Iridectomy
*	86-LZU	Plug, Punctum (UNDER REVIEW 8/20/93)
*	86-LXP	Scleral Plug (UNDER REVIEW 8/20/93)

\*NOTE: The majority of these applications are likely to be Tier II, however, concerns about materials, indications for use, design, and special operating parameters could prompt transfer to Tier III.

### Tier III Products

Class III:

*	886.3600	Intraocular lens: multifocals; new design & new material monofocals.
*	886.3920	Eye valve implant: new designs; new materials
*	886.4270	Intraocular gas: new gas; special indications
*	886.4275	Intraocular fluid: new fluid; special indications
--	886.4280	Intraocular pressure measuring device
*	886.5918	Rigid gas permeable contact lens solution (e.g., IN EYE solutions with new ingredients, and new intended uses.)
*	886.5928	Soft (hydrophilic) contact lens solution (e.g., IN EYE solutions with new ingredients, and new intended uses.)
*	886.5925	Soft (hydrophilic) contact lens (e.g., new materials for extended wear, intended use beyond 7 days, and therapeutic uses).
*	886.5916	Rigid gas permeable contact lens (e.g., new materials for extended wear, intended use beyond 7 days, and therapeutic uses).
----	86-LZT	Epikeratophakos
----	86-LQE	Corneal Implant
----	86-LZR	Cyclodestructive Ultrasound Device
----	86-LZS	Excimer Laser System
----	86-LZT	Intracorneal Implant
----	86-LZQ	Tissue Adhesive For Ophthalmic Use
----	---	Contact Lens Disinfection Units (Non-Heat) (new design)

The following legend applies to these lists:

E	Exempt for 510(k).
NE	Not exempt for 510(k) already.
AC	AC powered.
C	Conditional, i.e., the CFR lists conditions which may need to be considered.
S	Standards and specifications need to be checked.
D	Dual Division reviews usual.
M	Materials concerns.
P	Performance data required.
S	Sterility concerns.

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M	886.3130	Ophthalmic conformer
M	886.3200	Artificial eye
M	886.3300	Absorbable implant (scleral buckling method)
M	886.3320	Eye sphere implant
M	886.3340	Extraocular orbital implant
M	886.3800	Scleral shell
S	886.4100	Radiofrequency electro-surgical cautery apparatus
S	886.4115	Thermal cautery unit
--	886.4150	Vitreous aspiration and cutting instrument
--	886.4170	Cryophthalmic unit
*	886.4390	Ophthalmic laser
*	886.4392	Nd:YAG laser for posterior capsulotomy (other surgical procedures Tier III)
--	886.4610	Ocular pressure applicator
--	886.4670	Phacofragmentation system
--	886.4690	Ophthalmic photocoagulator
M	886.4790	Ophthalmic sponge
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--	86-HPX	PMMA Contact Lenses
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