THIRD PARTY REVIEW GUIDANCE FOR VITREOUS ASPIRATION & CUTTING DEVICE PREMARKET NOTIFICATION (510(k))

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Diagnostic and Surgical Devices Branch
Division of Ophthalmic Devices
Office of Device Evaluation

Document Issued on: January 31, 1997

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to Mr. Denis L. McCarthy, Division of Ophthalmic Devices (HFZ-460), Center for Devices and Radiological Health, 9200 Corporate Boulevard, Rockville, Maryland 20850. For questions regarding the use or interpretation of this guidance, contact Mr. Denis L. McCarthy at (301) 594-2205.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

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I. INTRODUCTION

A. Guidance Introduction and Purpose

This document reflects the current review guidance for the Vitreous Aspiration and Cutting device. It is based on 1) current scientific knowledge, 2) clinical experience, 3) previous submissions by manufacturers to the Food and Drug Administration (FDA), and 4) the Food, Drug and Cosmetic Act, as amended, the Safe Medical Devices Act of 1990 as amended, and FDA regulations in the Code of Federal Regulations (CFR). Following advances in science and medicine, and any new amendments by the Congress to the device acts, these review criteria will be reevaluated and revised as necessary.

This document is an adjunct to the CFR and other FDA Guidance documents for the preparation and review of 510(k) submissions. It does not supersede those publications, but provides additional clarification on what is necessary before the FDA can clear a device for marketing. The submission must provide evidence (21 CFR 807.92 (a)(3)) that the device is SUBSTANTIALLY EQUIVALENT to a device legally marketed in the United States. In some cases, the performance of the device can be established by comparison of the device to a standardized reference method, in addition to the comparison to a legally marketed device.

The primary reference for the information required in a premarket notification (510(k)) for a device is found in 21 CFR 807.87. Substantial equivalence to a legally marketed device is to be established with respect to, but not limited to, intended use, design, energy used/delivered, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

B. Product Introduction

A Vitreous Aspiration and Cutting device is described in the FDA regulation, 21 CFR 886.4150 (a) as "an electrically powered device, which may use ultrasound, intended to remove vitreous matter from the vitreous cavity or remove a crystalline lens".

C. Regulatory Background

The invention and use of the Vitreous Aspiration and Cutting Device predates the May 28, 1976 effective date of the Medical Device Amendments to the Food. Drug, and Cosmetic Act. FDA has classified this generic type of device as a Class II medical device and regulates it under the provisions of Subchapter H, Part 807, Subpart E of the Medical Device Regulations. This provision is

known as "Premarket Notification Procedures" and is more commonly referred to as "510(k)". The latter refers to that part of the Medical Device Amendments legislation which pertains to devices which have been in commercial distribution prior to the inception of the Medical Device Regulations.

II. DESCRIPTION OF DEVICE

There are basically three Vitreous Aspiration and Cutting Device types: 1) full function, designed to incorporate the aspiration, cutting, infusion, and illumination functions in the device handpiece; 2) the divided system, currently the most commonly employed type, which is designed so that the cutting and aspiration functions are confined to the device handpiece, while illumination and infusion are provided by separate probes; 3) handpiece accessories to ophthalmic microsurgery systems, such as phacoemulsification devices, that are designed to provide only aspiration and cutting functions.

Some design elements for components of this generic type of device are noteworthy, for example, the cutter design (e.g., guillotine or rotating blade), and the location and size of the aspiration and infusion ports. The medical literature has indicated that rotating blade devices, as opposed to those featuring straight line oscillating cutting action, have the potential for exerting excessive traction on the retina when used for cutting vitreoretinal strands, because of observations of strand wrapping about the blade.

It is important to note that the cutting component for this generic type of device is pneumatically driven at speeds much lower than those used in conjunction with phacoemulsification tips used in cataract surgery. The phacoemulsification tip is driven piezoelectronically, or magnetically, at ultrasonic frequencies; therefore, generation of cavitation and heat must be taken into consideration for this device, while these factors are not of general concern for the Vitreous Aspiration and Cutting Device. The Vitreous Aspiration and Cutting Device may be marketed as sterile single use or reusable, or as non-sterile single use or reusable devices.

III. CLASSIFICATION AND TIER OF DEVICE

This device has been placed in Class II under section 513 of the Federal Food, Drug, and Cosmetic Act. This device is in Tier II. The appropriate panel is the Ophthalmic Devices Panel and its classification may be found in Part 886 of 21 CFR (Code of Federal Regulations); it is specifically identified under regulation number 886.4150.

IV. REQUIRED 510(K) INFORMATION

A. Introduction to Review

The following sections describe information needed to evaluate a 510(k) premarket notification. The purpose of the review is to determine substantial equivalence to a legally marketed device. For further information refer to the 510(k) manual, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices", which is available from the Division of Small Manufacturers Assistance (DSMA). DSMA may be reached at (800) 638-2041 or (301)443-6597.

The premarket notification for a device, device modification or accessory should be dated and must be signed by the applicant. It should contain a table of contents and a listing of tabs and appendices. It should have sequential page numbers.

The premarket notification must include a statement that the submitter believes, to the best of his/her knowledge, that all data and information submitted are truthful and accurate, and that no material fact has been omitted as set forth in 21 CFR 807.87(j).

B. Device Name

Both the trade name or proprietary name and the classification name of the device must be specified.

C. Classification

This device has been placed in Class II under section 513 of the Federal Food, Drug, and Cosmetic Act. The submission should specify the correct class. This device has been placed in Tier II. The tier should also be specified in the submission.

The Division of Small Manufacturers Assistance (DSMA) may be contacted for assistance in determining classification of devices. DSMA may be reached at (800) 638-2041 or (301)443-6597.

D. Applicant/Contact Person

The premarket notification should list the applicant's name and address, and specify a contact person and telephone number. The name and address of the manufacturer should be specified, including the establishment registration number,

if applicable. (Ref. 21 CFR 807.87(b)).

E. Device Description

The physical description of each device to be marketed should be provided. This should include a labeled diagram, photograph, schematic, etc., which includes all internal, external, assembled, unassembled, and interchangeable parts. The physical description should include the dimensional specifications such as length, width, height, diameter, weight, etc. and electrical specifications (i.e., power requirements). Hardware/software components, if applicable to the device or accessories, also should be specified. Any parts that are disposable, such as cutter blades, couplers, etc., should be identified.

If the device is sold in a set that includes accessories, the accessories are considered to be part of the device. They also should be identified and described with the same detail as above. Accessories that might be provided with this device might include infusion and illumination probes, and tubing sets. Labeling should state whether the accessory is sterile or non-sterile, single use or reusable. If any of the accessories have been previously marketed for the same intended use, certification of the preamendments status or the 510(k) number should be furnished, if known.

Malfunctions associated with devices can sometimes be attributed to user error. Therefore, ergonomics should be considered in the device design. A description of the ergonomic features (e.g. audible/visible alarms, control panel design, data presentation, etc.) should be provided, if appropriate.

The size and location of parts, and the readability of labeling and instructions for use, may also effect the safety and efficacy of the device, and should be discussed as appropriate. In some cases, testing of instructions may be necessary.

F. Description of Quality Assurance Program

An adequate summary description of the manufacturers quality assurance program should be provided.

G. Clinical Indication

The proposed clinical indications of the device should be clearly noted in the submission. They must be consistent with the design of the device and with proposed labeling. Clinical indications should be reflected (if necessary) in

laboratory and clinical study design and must be supported by the results.

H. Device Materials

An exact identification of all materials used to fabricate the device and its accessories should be provided, with a statement regarding any differences from pre-amendment devices or the proposed predicate device. If the materials are identical to those used in the pre-amendment or predicate device and are identically processed and sterilized, then this should be explicitly stated. This information should include all direct and indirect (e.g., through fluids) patient contacting materials.

If the direct or indirect patient contacting materials are reusable, then instructions on reuse and evidence that the components can be safely disinfected and/or sterilized should be provided along with a justification for the proposed level of disinfection/sterilization.

If the device includes an antimicrobial agent or other drug component that is subject of an approved new drug application (NDA) or over the counter (OTC) monograph, the application should provide a reference to those documents. Specify any differences between the approved drug product and the agent used in the device.

I. 510(k) Summary or 510(k) Statement

The safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification submission to include either (1) a summary of safety and effectiveness information in the premarket notification upon which an equivalence determination could be based (510(k) summary) or (2) a statement that safety and effectiveness information will be made available to interested persons upon request (510(k) statement). Safety and effectiveness information refers to information in the premarket notification submission, including adverse safety and effectiveness information, that is relevant to an assessment of substantial equivalence. The information could be descriptive information about the new and predicate device(s), or performance or clinical testing information.

J. Testing Results and Performance Data

When testing results and /or performance data are required to demonstrate the substantial equivalence of the device which is subject of the manufacturers premarket notification (510(k)) to legally marketed device, the requirements listed

below should be followed.

1. Presentation of Data

Tables and Graphs: Data should be provided in clearly labeled tables. Any symbols used should be keyed to a footnote or convenient reference page and described fully. Graphs may supplement data tables, but do not replace them. Graphs must be clearly labeled.

Published Literature: Published data or methods that are referenced in the submission should be provided. Reprints should be appended to the section in which they are referenced. All referenced reports and data should be summarized, and include an explanation of how they relate to the current submission. Referenced citations should be complete (e.g., title, author, volume, page, year).

Protocols and Data Analysis: Reports of any testing conducted with the device must include the study protocol (objectives, precise description of materials, experimental methods, controls), data/observations, statistical methods and analysis, results/conclusions, and comments. Raw data should not be submitted unless requested.

Reference to Submitted Data: In support of a 510(k) submission, an applicant may refer to information submitted to FDA in the past. If someone other than the applicant submitted the previous information, then a letter of authorization is required. The letter may come through the applicant, or directly from the original submitter. Including a copy of this information with the new submission will facilitate the review.

2. Biocompatibility Testing

Biocompatibility testing data should be provided on any direct or indirect patient-contacting materials that are not the same as the pre-amendment or predicate device or are differently processed or sterilized. If data is not provided, a justification should be included explaining why these data are not needed. Guidance for this type of testing is provided in the document entitled International Standards Organization ISO-10993, “Biological Evaluation of Medical Devices Part 1: Evaluation and Testing”. This document is used in conjunction with the ODE Guidance Memorandum #G95-1, “Use of ISO-10993". Copies of the above may be obtained from DSMA.

An exact identification of all colorants (inks, dyes, markings, radiopaque materials,

etc.) used to fabricate the device or accessory should be provided, if applicable. If the colorants are identical to the pre-amendments or substantially equivalent device, then this should be explicitly stated. A statement regarding any colorant changes from the pre-amendments or substantially equivalent device should be included. The manufacturer should provide biocompatibility testing data on any colorant changes that have been implemented that will contact the patient directly or indirectly. The information should indicate how the markings are processed (etched, bands, etc.) and whether the colorant contacts skin, mucosa, etc.

3. Electrical Safety

A certification that the device complies with an appropriate domestic or internationally recognized electrical safety standard should be provided. Alternatively, the manufacturer may supply electrical safety data to document the electrical safety of the device.

K. Performance Data

When necessary, the following data should be provided to demonstrate substantial equivalence to the predicate device with respect to functional performance: (1) bench testing, (2) preclinical/animal testing, (3) clinical testing, (4) postmarket testing, (5) software testing, (6) sterility information. These tests should be conducted in a manner similar to the actual use of the device. Where appropriate, statistically valid data should be collected to establish device performance. It is required that all preclinical/animal testing be performed in compliance with 21 CFR Part 58 Good Laboratory Practices (GLP) for nonclinical laboratory studies, or the testing must have requirements that are equivalent to those contained in the above cited regulation.

Bench testing should be conducted in accordance with accepted industry standards, or a description of the test methods and a justification for their use must be provided. Sampling (when necessary) should include a range of devices representative of the product line.

The compliance or noncompliance of the device with any available standards or guidance should be discussed, including performance, design, and testing provisions. If available standards or guidance are not used, an explanation should be provided.

Guidance for the information required in a premarket notification of a software

controlled device is provided in the FDA document entitled "Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review (draft 8/29/91)." A copy may be obtained from DSMA.

Complete information regarding the device and/or accessories that may be sold sterile should be provided, including: the sterilization method, sterilization cycle, validation method, specification of packaging materials, a description of the packaging integrity to ensure that sterility is maintained, sterility assurance level (SAL). The radiation dose should be provided for devices sterilized with radiation, and, for ethylene oxide (ETO) sterilized devices, the maximum levels of residuals of ETO, ethylene chlorohydrin, and ethylene glycol should be provided. If only parts of the device are sold sterile, the labeling should clearly identify the parts that are sterile and non-pyrogenic. Devices labeled as non-pyrogenic (pyrogen free) will require documentation of this claim. A description of the method used to make the determination of non-pyrogenicity (i.e., LAL or rabbit test) must be provided.

If the device and/or accessories are sold and labeled non-sterile or can be reprocessed, instructions on disassembly, cleaning, disinfection and/or sterilization should be provided. If appropriate, a statement that the device requires high level disinfection should be provided and compatible solutions and/or procedures for high level disinfection and/or sterilization should be identified. Accessories that are disposable should be labeled as single use.

Guidance on sterility issues is described in the ODE Bluebook Memo K90-1 "510(k) Sterility Review Guidance (2/12/90)." A copy may be obtained from DSMA.

Flash sterilization may not be the sole method cited in the device sterilization instructions; it may be included along with other traditional steam or other methods of sterilization. The manufacturer is required to provide adequate instructions for flash sterilization including the autoclaving parameters, such as the recommended time, temperature etc., and whether or not the device should be wrapped.

The Association for Practitioners in Infection Control (APIC) and the Center for Disease Control (CDC) have established definitions and guidelines for the selection and use of disinfectants. Both APIC and the CDC have identified this device as critical. It should be noted critical items are objects which enter sterile tissue or the vascular system. Critical devices must be free of all microorganisms, including bacterial spores, and require sterilization that is expected to destroy all microorganisms and bacterial spores. Sterilization can be performed using steam

under pressure, radiation, ETO gas, and chemical sterilants.

Attached to this document is a checklist form which may be utilized to assist in the review of 510(k) submission for the Vitreous Aspiration and Cutting Device.

L. Labeling

Proposed labels, labeling, educational materials, user manuals, provided with the device, and advertisements and promotional literature must be provided. Literature and labeling may not imply approval of the device in any manner.

The Vitreous Aspiration and Cutting Device must be labeled with the caution statement as delineated in 21 CFR 801.109(b)(1): "CAUTION: Federal law restricts this device to sale by or on the order of a physician."

A label includes any identification on the device itself and on the package in which it is stored and shipped. If possible, the label on the device should include the device name, company name, address, and phone number. The package label should include the items listed above, and the sterility status, expiration date, use status (single use/disposable etc.), quantity enclosed, size, intended use, and any other pertinent device specific information, such as electrical specifications (i.e., energy used/delivered).

Device labeling includes all the information required under 21 CFR 801.

1. The intended use statement should include specific indications, clinical setting, target population, anatomical sites, etc.

2. Directions for use should include, but are not necessarily limited to: a) instructions on how to prepare the device for use, b) how to operate the device, c) how to stop operation, d) a statement of which parts are single use/disposable or reusable, e) functional test procedures for the device prior to use.

If the device is to be labeled as reusable, adequate instructions about how to clean, disinfect, and sterilize the device must be included. Validation of changes expected in device function secondary to reprocessing must be described.

Maintenance and troubleshooting procedures (where necessary) should be

outlined, with instructions on how to perform the maintenance and how often, how and when to replace parts, instructions for purchase of replacement parts, and a company contact point if troubleshooting procedures fail.

3. Contraindications, precautions, warnings, and adverse effects should be included in the labeling of the device.

Guidance on labeling issues is described in ODE Bluebook Memo G91-1 "Device Labeling Guidance (3/18/91)." A copy may be obtained from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597.

M. Summary of Equivalence

A Summary of Equivalence comparing similar devices that are legally marketed in the United States must be provided. This includes devices in commercial distribution prior to May 28, 1976, the enactment date of the Medical Devices Amendments, and any new Class I, or Class II devices introduced subsequently. The summary should clearly review similarities and differences between the device proposed for marketing clearance and the predicate device to which it is claimed to be substantially equivalent. It may be appropriate to present this material in table form.

The device comparison should include the following considerations: intended use, design (e.g., hardware, software, configuration, materials specifications, mechanical and electrical specifications), sterilization method, biocompatibility factors, and any other device factors of similarity between the proposed and predicate devices and which form the basis for the claim of substantial equivalence.

The application should clearly state whether the substantially equivalent device is a pre-amendments device or a device which has a prior history of processing via the 510(k) regulatory mode. If the device has a 510(k) history, the document control number for previously cleared device(s), if known, should be cited in the application.

DEVICE MODIFICATION - For changes or modifications of existing devices that could significantly affect the safety or effectiveness of the device, or for marketing a device with a new indication for use, the 510(k) should include a detailed description and rationale for the changes.
The submission must show that the applicant has considered the possible effects

of the change on the safety and effectiveness of the device, as described in 21 CFR 807.87(g).

Valid scientific evidence must be provided to demonstrate that these differences do not affect the safety and effectiveness. This may include the same types of testing delineated in part K Performance Data, above. Certification should be provided regarding compliance with voluntary standards, if appropriate.

Additional guidance concerning device modifications is available in the draft FDA guidance titled, "Deciding When to Submit a 510(k) for Change to an Existing Device 1/10/97)." This document may be obtained from DSMA.

DEVICE KITS - If this device is to be marketed as a kit, all components of the kit must be described. The following is a recommended wording for a certification describing the components:

> I certify that the following components of my kit are either (1) legally marketed pre-amendments devices, (2) exempt from premarket notification (consistent with the exemption criteria described in the classification regulation(s) and the limitations of exemptions from Section 510(k) of the act (e.g. 862.9)), or (3) have been found to be substantially equivalent through the premarket notification process for the use(s) for which the kit is intended (i.e., I am not claiming or causing a new use for the component(s)).
>
> I further certify that these components are not purchased in "bulk" but are purchased in finished form, i.e., they are packaged, labeled, etc., consistent with their pre-amendments, exemption, or premarket notification criteria and status.

If the applicant cannot make the certification statement above (first paragraph) for each component of the kit, the components should be itemized without a pre-amendments, exemption, or premarket notification status. These kit components will undergo premarket notification review in parallel with the total kit review.

If the applicant cannot make the above referenced certification statement (second paragraph) for each component of the kit, these components should be itemized with a statement about whether they are pre-amendments, exempt, or have been found substantially equivalent through the premarket notification process. The applicant should describe how they are further processed (e.g., sterilized/resterilized, packaged/repackaged, labeled/relabeled, etc).
If the kit contains components which are subject to regulation as drugs, a

substantially equivalent determination will not apply to the drug component(s) of the device. Information on FDA requirements for marketing the drug component(s) in the kit can be obtained from the Center for Drug Evaluation and Research's Division of Drug Labeling Compliance at (301) 295-8063.

If the kit contains sutures, evidence must be provided that the sterilant employed for the kit does not come into contact with the sutures during the sterilization process. If sutures are components of the kit, the following conditions are required:

1. The labeling, packaging, and method of sterilization of the sutures cannot be changed without prior notification, review, and approval by FDA.

2. The suppliers of the sutures used in the kit cannot be changed without prior notification, review, and approval by FDA.

VI. TRUTHFUL AND ACCURATE STATEMENT

The submitter must provide a Truthful and Accurate Statement. This is a statement that the submitter believes to the best of his/her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted as described in 21 CFR 807.87.

FOR MORE INFORMATION

For more information contact:

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Device Review Checklist

	YES	NO
1- Device Type		
(a) handpiece	---	---
(b) divided system	---	---
(c) full function	---	---
2- Intended Use		
(a) same as predicate	---	---
3- Components or Accessories		
(a) cleared	---	---
(b) disposables	---	---
(c) reusables	---	---
4- Comparability Factors		
(a) predicate	---	---
(b) materials same as predicate	---	---
(c) materials documented (toxicology, biocompatibility)	---	---
(d) design similar to predicate	---	---
(e) technological features same as predicate	---	---
(f) new technology raising new safety & effectiveness issues	---	---
5- Sterility		
(a) same materials, same sterility method as predicate	---	---
(b) different materials, same sterility method as predicate	---	---
(1) new material compatible with sterility method	---	---
(c) same materials, different sterility method than predicate	---	---
(1) sterility method compatible with materials	---	---
(d) different materials, sterility method different from predicate	---	---
(1) sterility method compatible with materials	---	---
(e) other (i.e. device shipped non-sterile to be sterilized by user, or reusable device to be re-sterilized by user)	---	---
(1) adequacy of recommended sterility method documented	---	---
(2) user instructions for sterilization of device adequate	---	---
(f) complies with sterility informational requirements of Blue Book Memo 02/12-90-(K90-1)		
6- Labeling Status		
(a) sample label(s) and labeling submitted	---	---
(b) labels, labeling provide adequate description of		

device, intended use, user instructions, contraindications, or device related risks delineated	---	---