Guidance for Industry

GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS FOR ESOPHAGEAL AND TRACHEAL PROSTHESES

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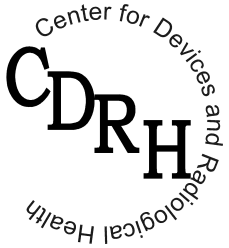

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Plastic and Reconstructive Surgery Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to the Plastic and Reconstructive Branch, HFZ-410, 9200 Corporate Boulevard, 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 Stephen Rhodes at (301) 594-3090 or by electronic mail at spr@cdrh.fda.gov.

Additional Copies

To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: http://www.fda.gov/cdrh/index.html) also provide easy access to the latest information and operating policies and procedures. Please specify number 006 when prompted for the document shelf number.

Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses

This document reflects the current review guidance for esophageal and tracheal prostheses devices. 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 Safe Medical Devices Act of 1990 and FDA regulations in the Code of Federal Regulations (CFR). As advances are made in science and medicine, and changes occur in implementation of Congressional legislation, 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 FDA believes is needed before a device can be cleared for marketing. The submission must provide evidence that the device is substantially equivalent in safety and effectiveness to a predicate device legally marketed in the United States.

Device Identifications

In 21 CFR 878, the following identifications are given for the esophageal and tracheal prostheses, respectively:

878.3610, an esophageal prosthesis is a plastic tube or tube-like device that may have mesh reinforcement that is intended to be implanted in, or affixed externally to, the chest and throat to restore the esophagus or provide pharyngoesophageal continuity.

878.3720, a tracheal prosthesis is a tubular device intended to be implanted to reconstruct the trachea.

Since these devices were first classified, metal self-expandable esophageal and tracheal prostheses have been found substantially equivalent to esophageal and tracheal prostheses, respectively. Therefore, these devices are also included under these classifications. These devices are intend to restore the structure and/or function of the esophagus and trachea or trachealbronchial tree. These devices may include any accessories and delivery systems used to deploy them.

The primary reference for the information required in a premarket notification (510(k)) for a medical 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. To expedite review of your 510(k) submission, please provide the information listed below. FDA recommends that your 510(k) submission include numbered pages, a table of contents and clearly titled sections.

I. DEVICE NAME

Provide the name of the device, including:

A. Classification name (i.e., esophageal or tracheal prosthesis);
B. Common name (i.e., esophageal or tracheal stent);
C. Trade or proprietary name; and
D. Intended use, including the method of device placement (endoscopically or percutaneously).

II. MANUFACTURER INFORMATION

Provide the following information about your company:

A. Establishment registration number;
B. Address of manufacturing site; and
C. Name, title and telephone and fax number of contact person.

III. DEVICE CLASSIFICATION

Provide the CFR classification regulation number for the device and any components or accessories. For example, esophageal and tracheal prostheses have CFR references of 21 CFR 878.3610 and 878.3720, respectively.

IV. DEVICE DESCRIPTION

Provide a detailed description of the proposed device. The description should include a labeled diagram, photograph or schematic drawing. The specifications, including the length, width, height, and diameter of each model should be included. The size ranges should be listed in terms of diameter (mm) and length (mm). Also, provide a detailed description of the deployment system for the device, including any accessories that are provided for this purpose. Finally, explain which components of the device may be disposable or reusable.

V. COMPARISON WITH PREDICATE DEVICE

Provide a comparison of the proposed device with the predicate device. The comparison should be presented in a clear and concise format (e.g., tabular). The description of the predicate device should include:

A. Proprietary and common name, model number and manufacturer
B. 510(k) reference number or pre-amendment status, if known
C. Indications for use
D. Technological characteristics, including design, materials, method of placement,

method of deployment, size ranges, etc.

E. Performance specifications (see section VIII below)

Also, provide copies of product literature for the predicate device, including labels, labeling, instructions for use, promotional materials, etc.

VI. CHANGE(S) or MODIFICATION(S)

If the purpose of the 510(k) is to describe a change or modification to an already legally marketed product, the submission should include the following:

A. Description of change or modification
B. Rationale for change or modification
C. Data to demonstrate that safety and effectiveness are not affected by the change or modification

VII. DEVICE MATERIALS AND BIOCOMPATIBILITY

A. An exact identification of all materials used to fabricate the device and deployment system, including any colorants (inks, dyes, markings, etc.), plasticizers or additives should be provided. Materials should be separated according to whether they have direct or indirect body contact and according to the duration of contact.

B. Biocompatibility data, as recommended by Blue Book memorandum, G95-1 "Use of ISO-10993 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" should be provided.

Esophageal and tracheal prostheses are considered implanted devices, tissue and bone contacting, extended duration (category C). The delivery systems are considered implanted devices, tissue and bone contacting, limited duration (category A). If the esophageal or tracheal prosthesis or delivery system is made of materials that have been well-characterized chemically and physically in the published literature (including any colorants, plasticizers or additives), and have a long history of safety in products with a similar intended use, the FDA will accept adequate justification for not conducting some or all of the following suggested tests. The tests should be performed on the materials of the final, ready-to-use device.

Esophageal and Tracheal Prostheses*:

- Cytotoxicity
- Sensitization (Guinea pig maximization with polar and non-polar extracts)
- Implantation
- Sub-chronic toxicity

- Chronic toxicity**

Delivery System:

- Cytotoxicity
- Sensitization (Guinea pig maximization with polar and non-polar extracts)
- Irritation or intracutaneous reactivity

***Genotoxicity testing is not required for this device because it is intended for implantation in patients with malignant strictures.**

**The device remains in the body for a prolonged duration. A long-term implantation study with histopathology may replace implantation and chronic toxicity.

VIII. PERFORMANCE TESTING - BENCH

Bench testing of esophageal and tracheal prostheses is required to establish substantial equivalence. The following tests are recommended:

A. Deployment Testing. This test is performed to validate the accuracy and repeatability of the delivery system. The device is usually deployed in a tube having similar characteristics (i.e., size, lubricity) to the esophagus or trachea or trachealbronchial tree. Ease of deployment and accuracy of placement are recorded. This test is only required for the largest diameter device that is to be marketed.

B. Expansion Force Testing. This test is performed to measure the force exerted by the metal self-expanding types of esophageal and tracheal prostheses during expansion. The predicate device should be tested with the same apparatus, and the results should be provided for both the proposed and the predicate devices. These test results should be provided for representative device diameters, including the smallest and the largest diameter devices that are to be marketed.

C. Compression Force Testing. This test is designed to measure the force required to compress the metal self-expanding types of esophageal and tracheal prostheses after expansion. Similar to the expansion force test, the predicate device should be tested with the same apparatus and the results should be provided for the proposed and the predicate devices. These test results should be provided for representative device diameters, including the smallest and the largest diameter devices that are to be marketed.

D. Dimensional Testing. This test is performed to verify the reproducibility of the metal self-expanding types of esophageal and tracheal prostheses length and diameter after deployment. These test results should be provided for every

diameter device that is to be marketed.

E. Corrosion Testing. This test is performed to establish the compatibility of the esophageal prosthesis materials with the corrosive environment in the esophagus. The device should be in contact with simulated gastric contents for a period of time that is representative of the implantation time of the device. After exposure to the simulated gastric contents, the tensile strength of the device material should be measured and compared to the untreated device. Visual inspection of the device using microscopy should also be performed. Accelerated exposure conditions may be used (e.g., elevated temperatures), however, a rationale should be provided on how the accelerated conditions are representative of the actual clinical use conditions.

F. Tensile strength tests. This test should be performed for any deployment system that includes components that are bonded or welded.

It is recommended that all data be presented in a clear tabular or graphical form. In describing each test protocol include the following: test objective, equipment used, rationale for test conditions, number of devices tested (FDA recommends that at least three devices of each type be tested for every test), results and analysis.

IX. PERFORMANCE TESTING - ANIMAL and CLINICAL

If the technology and/or materials of the esophageal or tracheal prosthesis and/or delivery system are significantly different from the predicate device, animal testing will be required. Clinical data may also be required, depending upon the extent of the difference between the proposed and predicate devices. FDA recommends that manufacturers contact us before submitting a 510(k) to discuss these issues if appropriate.

X. PERFORMANCE STANDARDS/ SPECIAL CONTROLS

There are no performance standards or special controls for esophageal and tracheal prostheses at this time.

XI. STERILITY

Guidance on sterility issues is described in ODE Bluebook Memorandum #K90-1, "Sterility Review Guidance (2/12/90)". A copy can be obtained from Division of Small Manufacturers Assistance (DSMA) at 1-800-638-2041. All sterile devices must meet the sterility assurance level (SAL) of 10^{-6}. Please provide the following information:

A. Sterilization method, if applicable
B. Sterilization validation method and SAL
C. Description of packaging method

D. Radiation dose or the maximum levels of residuals of ethylene oxide, ethylene chlorohydrin, and ethylene glycol which remain on the finished sterilized device, whichever is applicable.

XII. PROPOSED LABELING

A label includes any identification on the device and on the package in which it is stored and shipped. Additional guidance on labeling in issues is provided by Bluebook Memorandum #G91-1, "Device Labeling Guidance (3/18/91)." A copy can be obtained by contacting DSMA at the telephone number listed above. A draft or sample copy of the labeling should be provided in the submission. The labeling should include the device name, indications for use, U.S. point of contact, corporation name, address and phone number, sterility, expiration date (if applicable), and a statement whether the device is for single or multiple use. Instructions for use should be provided which clearly describe the indications for use, any warnings, precautions or contraindications for the device and clear instructions for proper deployment and positioning of the device. Also, provide copies of advertisement and promotional literature, if available.

XIII. 510(K) SUMMARY or STATEMENT

The Safe Medical Devices Act of 1990 (SMDA) requires all persons submitting a premarket notification to include either:

A. A summary of the safety and effectiveness information in the premarket notification, or

B. The following statement: *I certify that, in my capacity as (provide title) of (provide name of firm), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential information, as defined in 21 CFR 20.61.*

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. The 510(k) statement (part B above) must be signed and dated.

XIV. CERTIFICATION OF TRUTHFULNESS AND ACCURACY

Your submission must contain the following statement:

I certify in my capacity as (provide title) for (provide manufacturer's name), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

The above statement must be signed and dated by a representative of the company (not by a regulatory consultant).

XV. INDICATIONS FOR USE

The indications for use should be provided on a separate sheet of paper and should agree exactly with the indications provided in the device labeling.