Information for Keratome Manufacturers regarding LASIK; Final Guidance for Industry

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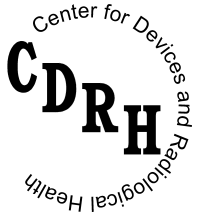

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Diagnostic and Surgical Devices Branch
Division of Ophthalmic and Ear, Nose, and Throat Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated. 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 Everette Beers, Ph.D., FDA/CDRH HFZ-460, 9200 Corporate Blvd., Rockville, MD 20850, phone (240)276-4200 , or email everette.beers@fda.hhs.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1376.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1376 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The Food and Drug Administration (FDA) has reexamined its 1996 position concerning the "LASIK" claim for keratomes. In 1996, after the approval of several refractive laser applications for the indication of Photorefractive Keratectomy (PRK), eye care practitioners proceeded to use the lasers *off-label* for Laser In-situ Keratomileuses (LASIK). Subsequently, the agency began receiving premarket notification (510(k)) submissions from keratome manufacturers with the request for the LASIK indication. We did not clear those original requests on the grounds that it was an off-label use of a device and the keratome by itself could not perform LASIK.

As you are aware, LASIK is no longer an off-label use for refractive lasers approved for that indication. Hence, we believe that a keratome can be immediately labeled for the LASIK indication if its corresponding 510(k) submission, already cleared by FDA, contained the following information:

1. specifications for the flap created by the device:

    a. type of hinge or flap (nasal or superior);
    b. thickness(s) of cut;
    c. flap diameter(s);
    d. hinge width(s); and ,
    e. accuracy and variability of the corneal flap produced.

2. protocols for the tests employed to validate the specifications listed in number 1, and their results;

3. descriptions of the means for creating the flap:

    a. methods and components used to produce variable hinge, diameter or thickness, if appropriate; and,

    b. means by which the blade is halted for the creation of a hinge or flap (e.g., a stopper on the racks); and,

4. instructions for creating a flap.

This will allow you to immediately label your device for LASIK, but it will not trigger an automatic change in the "recorded" indication statement for your device. The recorded indication statement, which can be retrieved from the FDA website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm), will remain as it was when the 510(k) submission was cleared. To change the recorded indication statement to include LASIK, you would need to submit a new 510(k) submission and enclose a new indication statement that includes LASIK. Please note the new 510(k) submission must contain all of the required elements of a 510(k) as described in 21 CFR 807.87. However, if you have not made any changes to your device, the new 510(k) submission can simply reference the previously cleared submission and enclose a new indication statement that includes LASIK.

If the 510(k) submission for your FDA cleared keratome did not contain the above criteria 1-4, you may not label your keratome for LASIK. You will need to submit a new 510(k) submission addressing the above items and receive FDA clearance before you can label your keratome for LASIK.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html