

K435233

SEP 15 1994

IV. SUMMARY OF SAFETY AND EFFECTIVENESS

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's "510(k) 'SE' Decision-Making Process Documentation" and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

Device Name: IOLAB Lacrimal Duct Catheter

Predicate Device(s) Name: Lacrimal Probe and Lacrimal Dilator

Indications Statement: Yes. The new device and the predicate devices have the same indications statement. Both are indicated for use in the nasolacrimal duct system.

Intended Use: Yes. The new device and the predicate devices are intended for single-use during dilatation of an obstructed nasolacrimal duct system to correct epiphora.

Technological Characteristics: No. The design of the predicate device is such that the outside diameter is fixed. Both the probe and the dilator are not adjustable in diameter size. The IOLAB lacrimal duct catheter has an adjustable diameter specific to the patient anatomy due to the use of an inflatable balloon.

The new characteristics do not raise new types of safety or effectiveness questions based on the fact that the IOLAB lacrimal duct catheter does not create a new indication for use.

Based on the 510(k) "Substantial Equivalence" decision-making process and the information provided herein, we conclude that the new device is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

Contact Person: Susan H. Caballa
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Date: October 29, 1993

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Quest Medical, Inc.
c/o Ms. Susan H. Caballa
Director, Regulatory Affairs
IOLAB
500 IOLAB Drive
Claremont, CA 91711

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Re: K935233
Trade/Device Name: IOLAB Lacrimal Duct Catheter
Regulation Number: None
Regulation Name: Lacrimal Stents and Intubation Sets
Regulatory Class: Unclassified
Product Code: OKS
Dated (Date on orig SE ltr): June 15, 1994
Received (Date on orig SE ltr): June 17, 1994

Dear Ms. Caballa:

This letter corrects our substantially equivalent letter of September 15, 1994. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health