



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MANICO/Bloomington  
C/O Mr. James Redding, P.E  
P.O. Box 5504  
Bloomington, IN 47407-5504

FEB 13 2004

Re: K840837

Trade/Device Name: Translid Binocular Interactor (TBI)  
Regulation Number: 886.1630  
Regulation Name: Photostimulator  
Regulatory Class: Class II  
Product Code: 86HLX  
Dated: October 9, 1984  
Received: October 30, 1984

Dear Mr. Redding:

This letter corrects our substantially equivalent letter of March 25, 1985 regarding the Regulation Number, Regulation Name, Regulatory Class and Product Code.

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 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); good manufacturing practice requirements as set

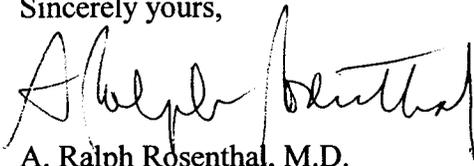
forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address

<http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal". The signature is written in a cursive style with a large initial "A" and a long, sweeping underline.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and

Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health