DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 6 2006

Ryazan State Instrument-Making Enterprise
c/o Mr. Neil E. Devine Jr.
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K060780
Trade/Device Name: Diaton Tonometer
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer & Accessories
Regulatory Class: Class II
Product Code: HKX
Dated: March 21, 2006
Received: March 22, 2006

Dear Mr. Devine

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 application (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.

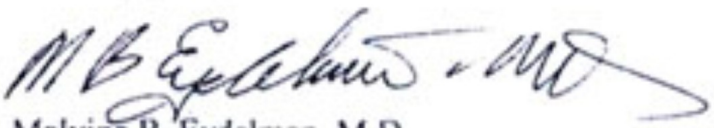
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 begin 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), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Annual Re-Registration

Annual Registration Successful

Get Help

FACILITY: ***JSCO RYAZAN STATE INSTRUMENT-MAKING ENTERPRISE, RYAZAN , RYAZANSKA YA OBLAST , RUSSIAN FEDERATION***

You have successfully updated your registration and listing information for 2015 .

Your registration will be valid through Dec 31, 2015 .

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2015 .

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices

You may contact the FDA with any questions at reglist@cdrh.fda.gov

The Owner/Operator Number for this Registration is: 9086205.

Facility

Registration Number:	3004058875
Initial Importer:	N
Facility Name:	JSCO RYAZAN STATE INSTRUMENT-MAKING ENTERPRISE
Address:	32 SEMINARSKAYA STREET RYAZAN , Ryazanskaya oblast , 390000 , RUSSIAN FEDERATION
DUNS Number:	
Foreign Trade Zone:	N
Facility URL:	
Other Business Trade Name(s):	

Owner/Operator Information

Contact Name:	EVGENIY - BARANKIN
Company:	RYAZAN STATE INSTRUMENT-MAKING ENTERPRISE
Address:	32 SEMINARSKAYA STREET , - RYAZAN , 390000 , RUSSIAN FEDERATION
Telephone:	749- 12 - 298453
Fax:	
E-mail:	boris@tonometerdiaton.com
DUNS Number:	

Official Correspondent Information

Contact Name:	BORIS - KUN
Company:	BICOM, INC.
Address:	151 EAST WALNUT STREET , – LONG BEACH , NEW YORK , 11561 , UNITED STATES
Telephone:	516 - 4313859
Fax:	888 - 2600606
E-mail:	boris@tonometerdiaton.com
DUNS Number:	

United States Agent Information

Contact Name:	BORIS KUN
Contact Title:	Mr
Business Name:	BICOM, INC.
Address:	151 EAST WALNUT STREET LONG BEACH, New York, 11561, UNITED STATES
Phone:	516-4313859 -0
Fax:	888 -2600606
DUNS Number:	
E-mail Address:	boris@tonometerdiaton.com

Device Listings

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities	Importers
E397476	K060780	HKX	TONOMETER, AC-POWERED	Manufacturer	BICOM Inc.

Date of Initial Registration: 2006-04-24 13:04:28.0

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