K062412

510 (k) Summary
Section 3

February 23rd 2006

NOV - 6 2006

1 Submitter

Keeler Instruments Inc
456 Parkway
Broomall PA. 19008
USA.

Contact: Mr. Eugene r. Van Arsdale
Marketing Manager
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2 Name of Device

Proprietary Name: Cryomatic System and Probes comprising of:
a) Cryomatic Console
b) Cryomatic Probes
Common Name Ophthalmic Cryo. Systems and Probes

Device Classification: Cryogenic Surgical devices have been placed in Class II as per 21 CFR Regulation Number 886.4170 and assigned the Product Code 86HRN

3 Predicate Devices

The components of the Cryomatic System are substantially equivalent to the following legally marketed devices:

K992954	Keeler Cryomaster and Probes
K874555	Keeler ACU 22 XT Ophthalmic Cryo unit.

This statement is based on the similarity of the subject device to the predicate devices in intended use, materials, design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2006

Keeler Instruments Inc.
c/o Mr. Eugene R. Van Arsdale
456 Parkway
Broomall, PA 19008

Re: K062412
Trade/Device Name: Cryomatic System & Probes
Regulation Number: 21 CFR 886.4170
Regulation Name: Cryophthalmic unit
Regulatory Class: II
Product Code: HRN
Dated: October 18, 2006
Received: October 20, 2006

Dear Mr. Van Arsdale:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062412

Device Name: Cryomatic System & Probes

Indications for Use:

The Keeler Cryomatic System and probes are for use in ophthalmic surgery in cryopexy for retinal detachment, cyclo destructive procedures in refractory glaucoma, extraction of fragments within the vitreous cavity, cataract extraction, cryo destruction of lash follicles for trichiasis, and treatment of retinopathy of prematurity (ROP)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marsha L. Burke Nicholas

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

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