510(k) Summary

Introduction

This summary is intended to comply with requirements of the SMDA and 21CFR§807.92. FDA may make this summary available to the public within 30 days following a finding of substantial equivalence.

510(k) Applicant

Meditron GmbH
Postrasse 19-21
D-66333 Voelklingen, Germany

510(k) Correspondent

Robert N. Clark, President and Senior Consultant
Medical Device Regulatory Advisors
13605 West 7th Ave.,
Golden, CO 80401 USA

Date Prepared

May 19, 2006

Trade Name of Device

Contact Lens Ophthalmodynamometer

Classification Name

Polymethylmethacrylate (PMMA) diagnostic contact lens

Classification

Regulation: 21CFR§886.1385
Product Code: NYK, Class II

Device Description

The Meditron Contact Lens Ophthalmodynamometer is a classic Goldmann three-mirror examination contact glass that has been adapted with precision electronic sensors for continuous measurement of pressure applied to the eye. Electronic signals from the sensors are used to determine pressure values, which are then displayed on the device's LCD display.

The patient contact portion of the examination glass consists of a curved shell of acrylic plastic (PMMA) that is applied for a short period of time directly on the globe or cornea of the eye. PMMA is commonly used as a material in examination contact glasses having the same intended purpose.

The mirror angles are the same as the original Goldmann and predicate devices: 59/66/73 degrees.

Intended Use

The device is indicated for examination of the ocular fundus, vitreous and retinal structures, while manually applying force to the eye with the contact lens. The device measures and displays the amount of force that is applied to the eye.

Predicate Device

K051103 - Haag-Streit Contact Glasses manufactured by Haag-Streit USA Inc, Mason, Ohio.

Voluntary Standards

EN 60601-1 / IEC 60601-1, "Medical Electrical Equipment - Part 1: General Requirements for Safety"

EN 60601-1-2 / IEC 60601-1-2, "Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests"

ISO 13485:2003, "Medical devices – Quality management systems – Requirements for regulatory purposes"

ISO 14971, "Medical devices – Application of risk management to medical devices"

Laboratory Testing

Repeatability and reproducibility of the device was determined under simulated use conditions. All results of the study were within acceptable tolerances.

Risk Management

This device has been designed to either completely eliminate or mitigate known health hazards associated with the use of the device. Health hazard risk reduction has been accomplished by rigorous application of a risk management program.

The user must be qualified in ophthalmic examination procedures, and must be familiar with all labeling and instructions for use associated with the device.

Meditron GmbH believes that the Contact Lens Ophthalmodynamometer is safe and effective when used as instructed by knowledgeable and trained personnel, and is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meditron Gmbh
c/o Mr. Robert N. Clark
Medical Device Regulatory Advisors
13605 West 7th Avenue
Golden, CO 80401

MAY 24 2006

Re: K052674
Trade/Device Name: Contact Lens Ophthalmodynamometer
Regulation Number: 21 CFR 886.1385
Regulation Name: Polymethylmethacrylate (PMMA) diagnostic contact lens
Regulatory Class: II
Product Code: NYK
Dated: April 26, 2006
Received: April 28, 2006

Dear Mr. Clark:

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.
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): K052674

Device Name: Contact Lens Ophthalmodynamometer

Indications for Use:

The device is indicated for examination of the ocular fundus, vitreous and retinal structures, while manually applying force to the eye with the contact lens. The device measures and displays the amount of force that is applied to the eye.

Prescription Use X (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ming-Chun Shih

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

510(k) Number 052674