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MAR 2 4 2004

510(k) Summary for MicroOptical's Critical Data Viewers

1. SPONSOR

The MicroOptical Corporation
Westwood, MA

Contact Person: Mark Spitzer, Ph.D., Chief Executive Officer
781-326-8111

2. Device Name

Proprietary Name: Models MD-3 and MD-6
Common/Usual Name: Head-mounted display system
Classification Information:

Head-mounted display systems have been classified as Class II devices under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Laparoscope and accessories	GCJ	876.1500	General Surgery

3. PREDICATE DEVICES

MicroOptical's Critical Data Viewers are substantially equivalent to the Nomad ND1000M Augmented Vision System, 510(k) No. K030940 and the Vista Head Mounted Display System (510(k) No. K961800).

4. DEVICE DESCRIPTION

MicroOptical's Critical Data Viewers contain an LCD display unit, non-prescription safety glasses, a control box with signal converter and battery mount, cables from viewer to control box and from control box to signal source, a lithium-ion rechargeable battery and a battery charger. The LCD display unit is mounted on a pair of non-prescription safety glasses and is connected via a four-foot cable to a small battery-powered control box that can be clipped onto a belt. A cable from the control box connects the control box to the video source. The battery is recharged using a separate battery charger. MicroOptical's Critical Data Viewers operate using a standard VGA signal and displaying it onto a small LCD.

5. INTENDED USE

MicroOptical's Critical Data Viewers are intended to display video images or patient data while mounted in front of the user's eye(s) anytime a video display is used. Typical applications include display of images from endoscopic cameras, ultrasound imaging systems, magnetic resonance imaging systems, or display of data from any type of patient monitor.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

MicroOptical's Critical Data Viewers are similar to the predicate devices in terms of indication, display format, field of view and focal range.

7 PERFORMANCE TESTING

MicroOptical's Critical Data Viewers have been subjected to standard optical, electrical, firmware, and mechanical tests to demonstrate the acceptability of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2004

The MicroOptical Corporation
c/o Mr. Daniel J. Dillon, RAC, CQA-Biomedical
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K040244
Trade/Device Name: MD-3 and MD-6 Critical Data Viewers
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 2, 2004
Received: February 3, 2004

Dear Mr. Dillion:

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) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040244

Device Name: MD-3 and MD-6 Critical Data Viewers

Indications for Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040244