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K993223

XII. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Robert McClane, Mediphotonix, LC, 484 H Street, Salt Lake City, UT 84103, phone: 801-363-4418.

I. Classification: Class II and Class I.

II. Common or usual name: Curing and whitening light.

III. Proprietary Name: RapiCure 2000™ Curing and Whitening Light

IV. Registration No.: In process

V. Classification Name: Tooth-shade resin (Accessory) EBF, Class II; and, Heat source for bleaching teeth EEG, Class I.

VI. Performance standards: None established under section 514.

VII. Description: The RapiCure 2000 is a high pressure mercury light source filtered and transmitted through an optical fiber for the curing of composite resins, as an aid in the whitening of teeth, and for other dental purposes. The device emits filtered light in the range from 400 to 500 nm. It accepts voltages from 100-230 VAC.

VIII. Labels and Labeling: Labels and Instructions for Use are provided. Competitive labels and labeling are provided and the products are compared.

IX. Indications for Use: source of illumination for curing dental restorative materials, and for tooth whitening activities.

X. Substantial Equivalence: RapiCure 2000™ Curing and Whitening Light is substantially equivalent to the Plasma Arc Curing system cleared by American Dental Technologies in K-952333, to the Apollo 95 curing and whitening system cleared in K-981948 by Dental/Medical Diagnostic Systems, Inc., to the Ardent Radiance Curing Light cleared by Air Techniques, Inc., in K-982615, to the Spectrum 800 Curing Unit, cleared by Dentsply in K-982318, the CU-100A Light Cure Unit cleared in K-980792, the O-Luxpro V/Q-Luxpro II Light Unit cleared in K-980793 and several other curing lights cleared under code EBF as accessories to composite materials classified as "tooth-shade resin and described in CFR 872.3690.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 1999

Mr. Robert McClane
Official Correspondent
Mediphotonix, LC
484 H Street
Salt Lake City, UT 84103

Re: K993223

Trade Name: Rapicure 2000 (Curing and Whitening Light)
Regulatory Class: II
Product Code: EBZ
Dated: September 21, 1999
Received: September 27, 1999

Dear Mr. McClane:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K993223

IX. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: RapiCure 2000 ™ Curing and Whitening Light.

This device is intended for use:

1. As a source of illumination for curing dental restorative materials,

2. Assisting in the whitening process in a dental office.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993223