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K043302

000003

510(k) Summary

Date prepared: September 22, 2004

Submitter/Owner:
Nova Ranger, Inc.
9885 Mesa Rim Rd.
Suite 127
San Diego, CA 92121

Contact person:
Curtis M. Egan
16787 Bernardo Center Drive, Suite A-1
San Diego, CA 92128

Phone number: (858) 675-8200

Fax number: (858) 675-8201

Proprietary name: Nova-Pulse

Common name: Nova-Pulse

Classification: Class II. 872.6070 Ultraviolet activator for polymerization

Product Code: EBZ

Substantial equivalence claimed to:

1. K000393 – Nova Cordless™ Curing Light

Description:

The Nova-Pulse cordless battery operated hand-held light is a cordless curing light using light emitting diodes. No filters are required to bloc out harmful and unnecessary rays. The light produced by these diodes is specifically in the optimum curing range of 430 to 500 nanometers

Intended use:
Source of illumination for curing dental restorative materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Nova Ranger, Incorporated
C/O Mr. Curtis M Egan
Regulatory Specialist
Certified Software Solutions, Incorporated
16787 Bernardo Center Drive, Suite A-1
San Diego, California 92128

Re: K043302
Trade/Device Name: Nova-Pulse Cordless Curing Light
Regulation Number: 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: December 20, 2004
Received: December 23, 2004

Dear Mr. Egan:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Janette Y. McCain M.D. FOR DR. CHIU LIN

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(Attachment I)

Indications for Use

510(k) Number (if known): N/A K043302

Device Name: Nova-Pulse Cordless Curing Light

Indications For Use:
Source of illumination for curing dental restorative materials.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (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)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K043302