K040606

APR 2 8 2004

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. Submittor Information

SATELEC
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FRANCE
Telephone: 011-33-56-34-06-07

Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: March 26, 2004

B. Device Identification

Common/Usual Name:	Polymerization Light-Curing Device
Classification Name:	Ultraviolet Activator for Polymerization
Proprietary Name:	Mini L.E.D. OEM Module

C. Identification of Predicate Device(s)

The Mini L.E.D. OEM Module is substantially equivalent to the following previously cleared and currently marketing device:

Satelec Mini L.E.D. (K032465)

D. Device Description and Intended Use

The Satelec Mini L.E.D. OEM Module is classified as an Ultraviolet Activator for Polymerization (21 C.F.R.§ 872.6070) because it is a device intended for the photo-polymerization of light cured dental materials, restorative composite materials, and orthodontic bonding and sealing materials. The Mini L.E.D. OEM Module is a universal photo-polymerization light curing source and producing visible blue light in the 430 to 480 nm waveband of the spectrum with a power density comprised between 1,000 W/cm^2 (Universal 7.5 mm light-guide) and 2,000 W/cm^2 (BoosterTip 5.5 mm light-guide). These power densities are sufficient for the Mini L.E.D. product intended uses, namely:

- photo-polymerization in the 430-480 nm waveband of visible light cured (VLC) dental materials,
- photo-polymerization in the 430-480 nm waveband of visible light cured (VLC) restorative composite materials, and
- photo-polymerization in the 430-480 nm waveband of visible light cured (VLC) orthodontic brackets, and orthodontic bonding and sealing materials.

E. Substantial Equivalence

The Satelec Mini L.E.D. OEM Module has nearly identical technical characteristics and intended uses as the 510(k) cleared light curing unit, the Satelec Mini L.E.D. (K032465), for the photo-polymerization of dental materials, restorative composite materials, and polymerization of bonding and sealing materials. This device is well established and has been determined to be safe and efficacious.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 8 2004

SATELEC
C/O Ms. Jaqueline E. Masse
Senior Consultant
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K040808
Trade/Device Name: Mini LED OEM Module
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: March 26, 2004
Received: March 29, 2004

Dear Ms. Masse:

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) 594-4613. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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,

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

Enclosure

510(k) Number (if known): K040808

Device Name: **Mini L.E.D. OEM Module**

Indications For Use:

Polymerization of light-cured dental materials
Polymerization of restorative composite materials
Polymerization of bonding and sealing materials.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard Botz DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K040808

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)