K972006

JUL 10 1997

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

A. Submittor Information

SATELEC
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FRANCE

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Contact Person: Pascal Dupeyron
Regulatory Affairs

Date Prepared: May 28, 1997

B. Device Identification

Common/Usual Name: Polymerization Light-Curing Device
Proprietary Name: ACTA OEM Module

C. Identification of Predicate Device(s)

The ACTA OEM Module is substantially equivalent to its predicate, device, ACTA (K961735) previously cleared and currently marketed.

D. Device Description

The ACTA OEM Module is a sub-assembly of the ACTA Polymerization Light Curing Device which received 510(k) clearance for the polymerization of light-cured dental materials, the polymerization of restorative composite materials, and the polymerization of bonding and sealing materials (K961735) on July 31, 1996. The ACTA OEM Module maintains all the same functions and main components of the ACTA: it is a stand-alone sub-assembly manufactured by SATELEC with all the same components and materials used in the manufacture of the original ACTA product, which can be used in standard dental units. The intended use, technical performance, and clinical indications are identical to those of its predicate device, the ACTA (K961735).

The ACTA OEM Module is a multi-purpose high intensity curing light generator kit to be marketed as a modular sub-assembly ("Original Equipment Manufacturer" - OEM) to manufacturers of dental units. The ACTA OEM Module, similar to its predicate device ACTA (K961735) operates by producing a visible blue light in the 400 to 520 nm waveband of the spectrum which enables the polymerization of composite materials.

The ACTA OEM Module light will cure all dental restoratives activated by light in that wavelength range. The radiation from the halogen bulb (44 watt) is selectively reflected, focused, and filtered to reduce the ultraviolet, infrared radiation and unneeded

visible light. Thus, only the radiation in the appropriate band is available to be absorbed by the light cured composite material. The radiation necessary for this process is in the wavelength range of 400 to 520 nanometers. A built-in filter system blocks the non-essential emitted radiation outside this blue radiation wavelength range.

An ergonomic handpiece is supplied with ACTA OEM Module Kit and is designed for ease of use, comfort and convenience. The handpiece casing is made of thermoplastic alloy. The handpiece houses the low voltage halogen lamp, and a lamp cooling fan. The kit also includes a disconnectable silicone cord, and a box which consists of one (1) deflector of ⌀ 0.3 in, one (1) optic fiber of ⌀ 0.3 in , four (4) protection caps, one (1) 44 W bulb, and one (1) instruction booklet. The Kit includes a connection diagram and PC board as well.

E. Substantial Equivalence

The technical characteristics of the ACTA are almost identical to those of the predicate, ACTA. Differences that exist between these devices relating to technical specifications, materials, physical appearance, and control systems are minor and do not affect the relative safety or effectiveness of the ACTA OEM Module relative to its predicate.

The ACTA OEM Module is intended for the polymerization of light-cured dental materials, polymerization of restorative composite materials, and polymerization of bonding and sealing materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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JUL 10 1997

Re: K972006
Trade Name: ACTA OEM Module
Regulatory Class: II
Product Code: EBZ
Dated: May 28, 1997
Received: May 30, 1997

Dear Ms. Masse:

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

510(k) Number (if known): K972006

Device Name: ACTA OEM Module

Indications For Use:

- Polymerization of light-cured dental materials,
- Polymerization of restorative composite materials, and,
- 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)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972006

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

(Optional Format 1-2-96)