MAY 1 6 2001 K011154

## IV. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Contact: ..... Dr. Andreas Petermann,
Manager U.S. Regulatory Affairs

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Date: ..... April 12, 2001

Name of Device

Proprietary Name: ..... Elipar™ FreeLight

Classification Name: ..... Ultraviolet Activator for Polymerization

Common Name: ..... Light-Curing Unit

Predicate Device

Elipar™ TriLight by ESPE..... K 984247

Description for the Premarket Notification

Elipar™ FreeLight is classified as an Ultraviolet Activator for Polymerization (21 C.F.R. § 872.6070) because it is a device intended to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of light through a rod. (Light-Curing Unit).

In difference to the predicate device, Elipar™ TriLight, Elipar™ FreeLight uses LEDs as the light sources. In contrast to halogen light units, Elipar™ FreeLight

emits light mainly in the wavelength range between 440 and 490 nm. The optimal fit of the wavelength range for the intended purpose ensures that the polymerization performance is similar to halogen light-emitting units, but at a lower light intensity.

For LEDs have a much lower power consumption than halogen light sources, it was possible to design Elipar™ FreeLight as a cordless handpiece driven by a rechargeable battery. The battery charger is integrated in the station of the unit.

Although, with the Elipar™ FreeLight a new technology is established, it has the same intended use and is substantially equivalent to ESPE's already 510(k) cleared light-curing unit Elipar™ TriLight.

The Elipar™ TriLight light source is well established and considered to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 6 2001

Mr. Andreas Petermann
Manager of US Regulatory Affairs
ESPE Dental AG
ESPE Platz
Seefeld, Bavaria
GERMANY

Re: K011154
Trade/Device Name: Elipar™ FreeLight
Regulation Number: 872.6070
Regulatory Class: II
Product Code: EBZ
Dated: April 12, 2001
Received: April 16, 2001

Dear Mr. Petermann:

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/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

K011154

## C. Statement of Indications for Use

Device Name: Elipar™ FreeLight

Indications for Use: Activator for light-induced intraoral polymerization of resinous dental pit and fissure sealants, restorative materials, bondings, or luting materials

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K011154