

2/25/99

K984247

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Name:ESPE Dental AG
 Street:ESPE Platz
 ZIP-Code, City:D-82229 Seefeld
 Federal State:.....Bavaria
 Country:Germany
 Contact:Dr. Andreas Petermann, Regulatory Affairs
 Phone:011-49-8152-700395
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 E-mail.....Andreas_Petermann@ESPE.de
 Date:.....11/16/1998

Name of Device

Proprietary Name:ELIPAR® TRILIGHT
 Classification Name:Ultraviolet Activator for Polymerization
 Common Name:.....Light-Curing Unit

Predicate Device

ELIPAR® (VISIO®) by ESPE(K803209)

Description for the Premarket Notification

ELIPAR® TRILIGHT 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).

ELIPAR® TRILIGHT has the same intended use and is substantially equivalent to ESPE's already 510(k) cleared light-curing unit ELIPAR® (VISIO®). Actually, the ELIPAR® TRILIGHT light source is a further development of the ELIPAR® (VISIO®) light source to provide the patient and user with more comfortable handling and more favorable properties. The ELIPAR® (VISIO®) light source is well established and determined to be safe and effective.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 1999

Dr. Andreas Petermann
Regulatory Affairs
ESPE Dental AG
ESPE Platz
D-82229 Seefeld
Bavaria, Germany

Re: K984247
Trade Name: Elipar® TriLight
Regulatory Class: II
Product Code: EBZ
Dated: November 16, 1998
Received: November 27, 1998

Dear Dr. 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.

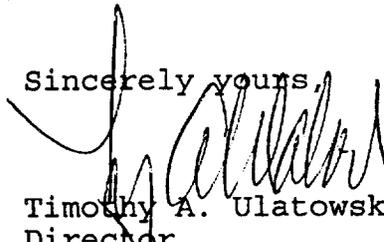
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

III. STATEMENT OF INDICATIONS FOR USE

Device Name:

ELIPAR® TRILIGHT

Indications for use:

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

Susan Runner

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

510(k) Number 1984247

Prescription Use _____
(Per 21 CFR 801.109)

Prescription _____
(Per 21 CFR 801.109)