K992895

SEP 8 1999

IV. 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

Establishment Registration Number: ... 9611385

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

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Date: ..... August 25, 1999

Name of Device

Proprietary Name: ..... IMPREGUM® F

Classification Name: ..... Impression material

Common Name: ..... Polyether based impression material

Predicate Device

IMPREGUM® F ..... K 853529

Description for the Premarket Notification

The modified IMPREGUM® F is classified as an impression material (21 C.F.R. § 872.3660) because it is a device intended to reproduce the structure of a patient's teeth.

ESPE is submitting this Special 510(k) for modifications of its polyether based impression material IMPREGUM® F. In particular one ingredient will be exchanged by

a chemical compound with comparable character and another one will be added. The modified IMPREGUM® F has the same fundamental scientific technology and the same intended use, therefore, we believe these modifications are eligible for the Special 510(k) process.

In this Special 510(k) Device Modification submission the chemical composition, the physical and mechanical properties, and the indications for use of both the un-modified IMPREGUM® F and the modified IMPREGUM® F are compared. Furthermore, ESPE's design control activities are shortly explained.

The modified impression material IMPREGUM® F has the following similarities to the unmodified IMPREGUM® F:

- IMPREGUM® F (modified) has the same intended use
- IMPREGUM® F (modified) is used by the same operating principle
- IMPREGUM® F (modified) incorporates the same basic chemical design
- IMPREGUM® F (modified) has the same shelf life
- IMPREGUM® F (modified) is manufactured and packaged using the same materials and processes

In summary the modified IMPREGUM® F described in this submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992895
Trade Name: Impregum® F
Regulatory Class: II
Product Code: ELW
Dated: August 25, 1999
Received: August 27, 1999

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4690. 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

K992895

Statement of Indications for Use

Device Name: IMPREGUM® F

Indications for use:

Dental impression material for:

Impressions for inlay, onlay, crown, and bridge restorations

Functional impressions

Fixation impressions

Implant impressions

Prescription use: ☒ Over-the counter use ☐

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992895