

JAN 28 2000

K994192

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ESPE Dental AG
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ZIP-Code, City: D-82229 Seefeld
Federal State: Bavaria
Country: Germany
Establishment Registration Number: ... 9611385
Contact: Dr. Andreas Petermann, Manager U.S.
Regulatory Affairs
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Date: December 10, 1999

Name of Device

Proprietary Name:..... IMPREGUM® PENTA® M MONOSOFT
Classification Name: Impression material
Common Name:..... Polyether based impression material

Predicate Device

IMPREGUM® PENTA® K 992897

Description for the Premarket Notification

IMPREGUM® PENTA® M MONOSOFT 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 to its polyether based impression material IMPREGUM® PENTA®. The modified material is characterized by

its reduced Shore hardness in comparison to IMPREGUM® PENTA®. The reduced Shore hardness of the set impression material results in increased user convenience because the set impression is easier to remove from the mouth. As an additional effect of the reduced Shore hardness, slight undercuts have no longer to be blocked out. The name of the modified material will be, however, IMPREGUM® PENTA® M MONOSOFT.

Like IMPREGUM® PENTA®, IMPREGUM® PENTA® M MONOSOFT is an impression material designed for the monophasic technique. Like for example IMPREGUM® PENTA® and PERMADYNE® PENTA®, IMPREGUM® PENTA® MONOSOFT is another material intended to be used in ESPE's automatic mixing, dosing and dispensing device, PENTAMIX®. PENTAMIX® 2 received recently 510(k) clearance (K 991913).

IMPREGUM® PENTA® M MONOSOFT has the same fundamental scientific technology, the same intended use and is applied by the same technique as IMPREGUM® PENTA®, therefore, we believe these modifications are eligible for the Special 510(k) review 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 unmodified IMPREGUM® PENTA® and the modified IMPREGUM® PENTA® M MONOSOFT are compared. Furthermore, ESPE's design control activities are shortly explained.

The modified impression material IMPREGUM® PENTA® M MONOSOFT has the following similarities to the unmodified IMPREGUM® PENTA®:

- IMPREGUM® PENTA® M MONOSOFT has the same intended use
- IMPREGUM® PENTA® M MONOSOFT is used by the same operating principle
- IMPREGUM® PENTA® M MONOSOFT incorporates the same basic chemical design
- IMPREGUM® PENTA® M MONOSOFT has the same shelf life
- IMPREGUM® PENTA® M MONOSOFT is manufactured and packaged using the same materials and processes

All chemical components of IMPREGUM® PENTA® M MONOSOFT are already part of the predicate device IMPREGUM® PENTA® or are contained in other 510(k) cleared impression materials manufactured by ESPE. Therefore, we believe that additional biocompatibility testing is not required.

In summary the modified IMPREGUM® PENTA® M MONOSOFT described in this 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

**JAN 28 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994192
Trade Name: Impregum® Penta® M MonoSoft
Regulatory Class: II
Product Code: ELW
Dated: December 10, 1999
Received: December 13, 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

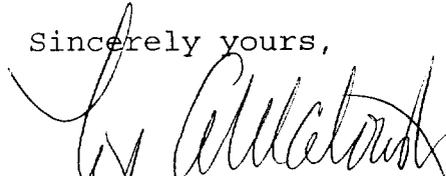
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (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

K994192

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K994192

Device Name: IMPREGUM® PENTA® M MONOSOFT

Indications for use: Dental impression material for automatic mixing and dispensing in a PENTAMIX® or PENTAMIX® 2 mixing device, resp.:

Impressions for inlay, onlay, crown, and bridge restorations

Functional impressions

Fixation impressions

Implant impressions

Prescription use:

Over-the counter use

Susan Runo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994192