

K994190

JAN 27 2000

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: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 U.S.
Regulatory Affairs

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Date: December 10, 1999

Name of Device

Proprietary Name:..... IMPREGUM® GARANT® L DUOSOFT

Classification Name: Impression material

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

Predicate Device

PERMADYNE® GARANT® K 953374

Description for the Premarket Notification

IMPREGUM® GARANT® L DUOSOFT 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 PERMADYNE® GARANT®. IMPREGUM® GARANT® L DUOSOFT is



intended to be used together with ESPE's new impression material IMPREGUM® PENTA® H DUOSOFT in a one-step and two-step "putty wash" technique.

Like PERMADYNE® GARANT®, IMPREGUM® GARANT® L DUOSOFT is a low viscosity impression material for mixing, dosing and dispensing in the GARANT® dispenser.

IMPREGUM® GARANT® L DUOSOFT has the same fundamental scientific technology, the same intended use and is applied by the same technique as PERMADYNE® GARANT®, 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 PERMADYNE® GARANT® and the modified IMPREGUM® GARANT® L DUOSOFT are compared. Furthermore, ESPE's design control activities are shortly explained.

The modified impression material IMPREGUM® GARANT® L DUOSOFT has the following similarities to the unmodified PERMADYNE® GARANT®:

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

All chemical components of IMPREGUM® GARANT® L DUOSOFT are already part of the predicate device PERMADYNE® GARANT® 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® GARANT® L DUOSOFT described in this submission is, in our opinion, substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2000

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

Re: K994190
Trade Name: Impregum® Garant® L DuoSoft
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.

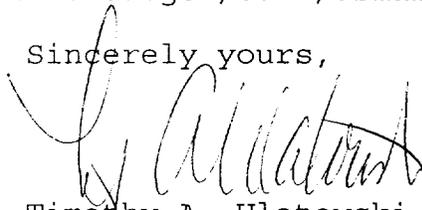
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

K994190

D. Statement of Indications for Use

Device Name: IMPREGUM® GARANT® L DUOSOFT

Indications for use: Dental impression material for mixing and dispensing in a GARANT® dispenser:
Impressions for inlay, onlay, crown, and bridge restorations
Functional impressions
Fixation impressions
Implant impressions

Susan Runne

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
File # Number K994190

PRESCRIPTION DEVICE