



- IMPREGUM® PENTA® DUOSOFT is manufactured and packaged using the same materials and processes

All chemical components of IMPREGUM® PENTA® DUOSOFT are already part of the predicate device PERMADYNE® 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® DUOSOFT described in this 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: K994193  
Trade Name: Impregum® Penta® 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

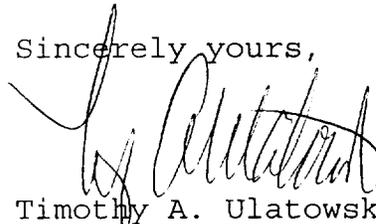
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K994193

D. Statement of Indications for Use

Device Name: IMPREGUM® PENTA® H DUOSOFT  
IMPREGUM® PENTA® L DUOSOFT

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

*Susan Runner*

(Division Sign-Off)  
Division of Dental, Infection Control,  
& General Hospital Devices  
CER Number K994193