JUL 26 1999

K991983

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
Establishment Registration Number 9611385
Contact: ..... Dr. Andreas Petermann, Regulatory Affairs
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Date: ..... June 1, 1999

Name of Device

Proprietary Name: ..... PENTAMIX® 2
Classification Name: ..... Amalgamator, Dental, AC-Powered
Common Name: ..... Automatic mixing device for ESPE PENTA impression materials

Predicate Device

CAPMIX® by ESPE ..... K 891064

Description for the Premarket Notification

ESPE's new mixing device for impression materials, PENTAMIX® 2, is comparable and substantially equivalent to an AC-powered dental amalgamator. It is therefore a class I device which has been exempted from premarket notification requirements (21 C.F.R. § 872.3100). However, consistent with 21 C.F.R. § 872.9, ESPE is submitting this premarket notification because the intended use of PENTAMIX® 2 is significant different to that of CAPMIX® (21 C.F.R. § 872.9 a). Furthermore, ESPE wants to give evidence that safety and effectiveness are only warranted when

PENTAMIX® 2 is used together with ESPE's especially designed PENTA impression materials.

Since 1993, ESPE has been marketing the predecessor of PENTAMIX® 2, PENTAMIX®, successfully all over the world. The high level of acceptance, together with permanent contact between ESPE and its customers, led first of all to an expansion of the PENTA product family. However, through this dialogue, ESPE also became aware that many users wanted a faster working mixing unit. This wish has now been met with PENTAMIX® 2.

The predecessor of PENTAMIX® 2, PENTAMIX® was determined by ESPE to be substantially equivalent to a mixing spatula/mixing bowl, and, therefore did not go through the 510(k) process. However, the PENTAMIX® device was reviewed by the FDA in connection with ESPE's 510(k) submissions for its PENTA impression materials PERMADYNE® PENTA (K 953027), RAMITEC® PENTA (K 952693), IMPREGUM® PENTA (K954192), DIMENSION® PENTA (K 960547), and POSITION® PENTA (K 974231).

We are aware of the fact that the PENTAMIX® 2 could be marketed without 510(k) clearance in the U.S.A. With this 510(k) submission we want to focus on the PENTAMIX® 2 system to claim, that safe handling and satisfying results for patient and user are only ensured when PENTAMIX® 2 is used together with genuine ESPE PENTA impression materials.

The basis for our substantial equivalence determination will be the PENTAMIX® which is a well-established, safe and effective medical device. Technical and performance data of the two PENTAMIX® devices will be compared to show that ESPE's further development PENTAMIX® 2 is as safe and effective as its predecessor. The predicate device CAPMIX® is used to provide a regulation number and a product code.

PENTA impression materials are provided in so called poly bags. Those have to be inserted in especially designed cartridges which ensure correct and simple handling of the materials with PENTAMIX®. In recent time, ESPE recognized that competitors copied the poly bags and sold those materials for the use with ESPE's PENTAMIX®. Due to the fact that there is no corresponding cartridge and to different

material characteristics, safety and effectiveness of the impression materials for the patient and user are not warranted in ESPE's point of view.

For patient and user safety features, ESPE is submitting this premarket notification to emphasize that safety and effectiveness of the impression process is only guaranteed when genuine PENTA materials are used with PENTAMIX® 2.

PENTAMIX® 2, as successor to PENTAMIX®, offers the same simple and convenient handling at 1.5 times the speed. The accustomed high mixing quality of impression materials remains unchanged. The higher dispensing speed achieved is, however, a significant safety factor in terms of working time for all indications, and equally represents a clear time saving. The PENTAMIX® 2 system permits more relaxed and cost-effective work, and is intended as another step towards greater precision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1999

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

Re: K991913
Trade Name: Pentamix® 2
Regulatory Class: I
Product Code: EFD
Dated: June 1, 1999
Received: June 7, 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) 594-4692. 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

K991913

III. STATEMENT OF INDICATIONS FOR USE

Device Name: PENTAMIX® 2

Indications for use: Automatic mixing, dosing and dispensing system for ESPE's PENTA impression and bite registration materials:

- IMPREGUM® PENTA
- PERMADYNE® PENTA H
- PERMADYNE® PENTA L
- RAMITEC® PENTA
- DIMENSION® PENTA H
- DIMENSION® PENTA H QUICK
- DIMENSION® PENTA L
- POSITION® PENTA
- POSITION® PENTA QUICK

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991913