K030588

MAY - 7 2003

Section 3.0 510(k) Summary

Submitted by:	Merz Dental GmbH Eetzweg 20 D-24321 Luetjenburg Germany Phone: + 49.4381.4030 Fax: + 49.4381.403100
Date of Summary:	This summary was prepared on February 20, 2003.
Device name:	Artegral, and Polystar Selection
Common Name:	Preformed Plastic Denture Teeth
Classification Name:	Denture, Plastic, Teeth: 21 CFR §872.3590, ProCode 76 ELM
Predicate Devices:	Dental Vipi Ltda: Acry Pan, Vipi Dent Plus, Biolux, Biolux V, New Dent, Dentoluxx, Vipi Dent N.H. and Vipi Dent V Preformed Plastic Denture Teeth (K022300).
Modifications:	Differences in available size, shape, and color.
Intended Use:	Artegral, and Polystar® Selection are intended for use as teeth in dentures.
Technological Characteristics:	Comparable chemical composition as the predicate.
Testing:	Performance and safety testing activities were conducted against recognized standards to establish the reliability characteristics of the new devices. Testing involved bench studies, and biocompatibility tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2003

Merz Dental GmbH
C/O Mr. James Delaney
EXPERTech Associates, Incorporated
100 Main Street, Suite 120
Concord, Massachusetts 01742

Re: K030588
Trade/Device Name: Artegral and Polystar Selection® Performed Plastic Denture Teeth
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: February 21, 2003
Received: February 25, 2003

Dear Mr. Delaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K030588

Device Name: Merz Dental GmbH Artegral, and Polystar® Selection preformed plastic denture teeth

Indications for Use: Artegral, and Polystar® Selection preformed plastic teeth are prefabricated devices composed of polymethylmethacrylate and cross-linking co-polymers of methacrylic acid (IPN) intended for use as teeth in dentures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulcey for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K030588

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)