NOV 0 1 2001

K012835

5. 510 (k) Summary

Submitter of 510(k): Wieland Edelmetalle GmbH & Co.
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Date of Summary: 2001-07-21

Trade name: Porta Maximum

Classification name: Alloy, gold based, for clinical use
Product code: EJT
C.D.R section: 872.3060
Classification: Class II

Legally marketed equivalent device: Argistar Bio 75PF

510(k) number: K955973

Device description

Porta Maximum is an extra-hard universal alloy with high contents of noble metals (83%), intended for dental technicians to fabricate dental restorations.

It has an indication which ranges from inlays/onlays and crowns up to long span bridges with two or more pontics and removable partials. It is free of copper and therefore suitable for telescopic and milling work.

Porta Maximum is highly corrosion resistant and has an excellent biocompatibility. It fully complies to the international standard ISO 9693 and fulfills the essential requirements of the European directive 93/42/ECC concerning medical devices.

Porta Maximum can be veneered with low-fusing dental ceramics with high expansion and with dental composites, in which the golden yellow color of the alloy provides an excellent basis for manufacturing aesthetically pleasing dental restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 1 2001

Dr. Gerhard Polzer
Director of Regulatory Affairs
Wieland Edelmetalle GmbH & Company
Schwenninger Strabe 13
Pforzheim,
GERMANY

Re: K012835
Trade/Device Name: Porta Maximum, Model 2066
Regulation Number: 872.3060
Regulation Name: Alloy, Gold Based, for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: October 18, 2001
Received: October 22, 2001

Dear Dr. Polzer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613 . 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Statement of indication for use

Porta Maximum is a universal gold-based dental alloy that can be used by dental technicians to fabricate dental appliances for patients.

It is intended for manufacturing

- Inlays/ Onlays
- Partial crowns
- Crowns
- Short span bridges
- Long span bridges
- Removable partials

and can be used for

- Telescopic and milling work

Porta Maximum can be veneered with low-fusing dental ceramics with high expansion as well as with dental-composites.

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012835