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K021733

Premarket Notification 510(k) Auropal 50

5. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2002-04-12

Trade name: Auropal 50

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

Legally marketed equivalent device: G-Cast
Manufacturer: Degussa AG

Device description

Auropal 50 is a dental gold-silver casting alloy (55% noble metals), intended for dental technicians to fabricate dental restorations.
On the basis of it's mechanical properties, Auropal 50 is a Type 4 casting alloy, according to ISO 8891.

The indications of Auropal 50 comprise inlays/onlays, crowns and short span bridges.

Auropal 50 is highly corrosion resistant and it fully complies with the requirement of the international standard ISO 8891 and fulfills the essential requirements of the European directive 93/42/ECC concerning medical devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik
GmbH & Co. KG
Schwenninger Strasse 13
75120 Pforzheim,
GERMANY

JUN 2 6 2002

Re: K021733
Trade/Device Name: Auropal 50
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: May 17, 2002
Received: May 28, 2002

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

510(k) Number (if known): K021733

Device Name: Auropal 50

Indications For Use:

Auropal 50 is a gold-silver casting alloy that can be used by dental technicians to fabricate dental appliances for patients.

It is intended for manufacturing

- **Inlays/Onlays**
- **Crowns**
- **Short span bridges**

Auropal 50 can be veneered with dental-composites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021733

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)