SEP 12 2002

Premarket Notification 510(k) **Auropal Solder M-1**

K022459

5. 510 (k) Summary

Submitter of 510(k): Wieland Dental + Technik GmbH & Co. KG
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Date of Summary: 2002-06-18

Trade name: AUROPAL SOLDER M-1

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

Legally marketed equivalent device: Argesol #615
510(k) number: K 942980

Device description

Auropal Solder M-1 is a dental brazing alloy, that can be used by dental technicians to fabricate dental appliances for patients. It is a pale yellow alloy with high contents of precious metals (Gold, Palladium and Silver: 82%).

Auropal Solder M-1 is suitable for use as a filler material in operations in which dental alloy(s) parts are joined to form a dental restoration, e.g. bridges.

It is intended as a primary solder for dental alloys with appropriate melting ranges and compositions, especially ECO E4, which is manufactured by Wieland Dental + Technik GmbH & Co. KG, Germany. In cases where secondary soldering is needed, Auropal Solder W-2 should be used.

Auropal Solder M-1 is highly corrosion resistant. It fully complies to the international standard ISO 9333 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

SEP 12 2002

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Dental + Technik GmbH & Company KG
Schwenninger Straβe 13
D-75179 Pforzheim
GERMANY

Re: K022459
Trade/Device Name: Auropal Solder M-1
Regulation Number: 21 CFR 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: July 22, 2002
Received: July 26, 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,

Patricia Cicenti /for

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

Enclosure

510(k) Number (if known): K022459

Device Name: Auropal Solder M-1

Indications For Use:

Auropal Solder M-1 is intended for use as a primary solder in operations in which dental alloy(s) parts are joined to form a dental restoration.

It should be used only together with recommended dental alloys with suitable melting ranges and compositions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

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

510(k) Number K022459

(Optional Format 1-2-96)