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K001041

WIELAND
Edelmetalle

Premarket Notification 510(k)

AGC Gold Electroforming System

7. 510 (k) Summary

Submitter:	Wieland Edelmetalle GmbH & Co. Schwenninger Str. 13 D-75179 Pforzheim Germany
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Date:	2000-03-21
Name of the device:	AGC Gold Electroforming System consisting of • Gold electrolyte AGC Micro • Gold electrolyte AGC Speed • AGC Goldbonder • AGC Galvanogold
Classification name:	Gold-based alloys and precious metal alloys for clinical use
Product code:	EJT
C.D.R section:	(872.3060)
Legally marketed equivalent device:	Midas Gold Electroforming System
510(k) number:	K955509

510 (k) Summary

The AGC Gold Electroforming System is a system designed to produce pure gold (>99.9%) substructures for dental restorations by the electroforming technique.

Originally developed by Wieland Edelmetalle in 1986 for producing crowns, the range of indications of the AGC Gold Electroforming System has been extended considerably.

At this time it is intended for manufacturing inlays, partial crowns, crowns, retainer crowns for small bridges with ceramic or acrylic veneers, as well as mesostructures (SupraCaps) in suprastructures on implants, and secondary crowns in the telescopic crown technology.

The galvanoforming procedure of the AGC Gold Electroforming System is as follows:

A dublicate die (super hard stone), or a primary telescopic crown, or an implant abutment has to be coated with conductive silver lacquer.
This working model is used as a cathode in an electroplating tank which is located in a specially designed unit. The AGC Gold electrolyte consists of an aqueous cyanide free Ammonium Gold Sulfite solution.
When the unit is turned on, positively charged gold ions will be deposited on the cathode, e.g. the conductive surface of the model, and form a gold layer.
The thickness of the layer depends on the duration of the operating time. It can be selected between 200 microns or 300 microns.
The operating time is 300 min and 415 min respectively in the case of the Gold electrolyte AGC-Micro or 85 min and 170 min respectively, in the case of the Gold electrolyte AGC-Speed (incisor crown).

Dental restorations:

AGC Galvanogold consists of pure gold (>99.9%) and has therefore an excellent biocompatibility and resistance against corrosion or tarnishing processes. In AGC restorations only new virgin gold is used. They are free of shrinkage cavities, pores, impurities and inclusions.

All common ceramic systems as well as low-fusing porcelains with high CTE can be fired on AGC Galvanogold. Due to the warm base color of AGC Galvanogold, this metal-ceramic crowns have an unequaled esthetic appeal.

AGC single crowns have the best marginal fit of all common techniques.

The long-term durability of AGC Galvanogold restorations has been proven by clinical studies since 1986.

AGC restorations have an extremely low plaque affinity.

The AGC restorations can be cemented with zinc phosphate cements as well as with modern glass ionomer cements.

Tooth preparation by the dentist is eased by the accommodating gold layer of constant thickness. Due to the high precision of the AGC Electroforming technique tooth preparation has to be carried out carefully. Tangential preparation is contra-indicated.

A short list of references concerning the topics mentioned above is given in Annex H.

Numerous scientific studies and application reports proved the enormous advantages of the AGC Gold Electroforming System (Annex I). The safety and efficacy of this system based on the intrinsic biocompatibility of pure gold and the successful clinical performance of this system in Europe.

The AGC Gold Electroforming System is in use in Europe since 1986 and a predicate product exists on the U.S.market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2000

Dr. Gerhard Polzer
Director, Regulatory Affairs
Wieland Edelmetalle GmbH & Co.
Schwenninger Straße 13
D-75179 Pforzheim
Germany

Re: K001041
Trade Name: AGC-Gold Electrolyte for AGC-Micro, AGC-Gold Electrolyte for AGC-Speed
Regulatory Class: II
Product Code: EJT
Dated: March 23, 2000
Received: March 31, 2000

Dear Dr. Polzer:

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

6. Statement of indication for use

The AGC Gold Electroforming System is a system designed to produce pure gold (>99.9%) substructures for dental restorations by the electroforming technique.

The AGC Gold Electroforming System is intended for manufacturing

- **inlays,**
- **partial crowns,**
- **crowns,**
- **retainer crowns for small bridges**

with ceramic or acrylic veneers as well as for

- **mesostructures (SupraCaps) in suprastructures on implants, and**
- **secondary crowns in the telescopic crown technique.**

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001041