

APR 2 1999

K 990670

510 (k) Summary

(a) (1) C. HAFNER GmbH & Co
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Contact person Dr. Helmut Knosp

Date: 1999-01-29

(a) (2) Name of device: Helioform
consisting of
HF-Goldkonzentrat
HF-Elektrolyt
Electrolytic gold

Classification name: gold based alloy

(a) (3) Legally marketed equivalent device:
Progold Electrocoating System
510 (k) number: K 980613

(a) (4) The Helioform System is used to fabricate i. e. inlays, onlays and crowns by a electroforming process. Electroformed gold framework that can be fitted with ceramic facings are an ideal combination of function, esthetic appeal and biocompatibility. The galvanofforming procedure of the Helioform System is as follows:

An electroconductive polyurethane duplicate die is used as a cathode in an electroplating tank. The electrolyte in this tank contains fine gold in solution (HF-Elektrolyt).

When the electric current between the anode and cathode is activated, positively charged gold ions will travel from the electrolyte to the cathode, where they are deposited and form a gold plating.

Galvanoformed parts are produced in Helioform technique using polyurethane dies. The dies are coated with a conductive silver spacer and serves as the cathode of the electroplating circuit.

The electrolyte consists of a non-cyanide gold sulfite solution to which non-cyanide gold concentrate (HF-Goldkonzentrat) is continuously released to replace the gold precipitated on the cathode.

When the electric current is turned on, gold will be deposited on the polyurethane die. The thickness of the layer depends on the duration of the live cycle (approximately 20 μm per hour). It can be selected between 200 - 400 μm .

The galvanoformed item contains only fine gold with a fineness of 99,99 %. The amount of material required is only about 60 % of what a comparable casting alloy with high gold content would require. All porcelains which are used together with ceramic alloys with coefficient of thermal expansion between 13,8 and 17,2 $\mu\text{m}/\text{m}\cdot\text{K}$ can be fired on galvanoformed Helioform items. Physical properties of galvanoformed Helioform gold are:

Density:	19,3 g/cm^3
Melting point:	1064 $^{\circ}\text{C}$
Vickers Hardness after galvanoforming:	100 HF
Vickers Hardness after firing on porcelain:	25 HV
Grain size after galvanoforming:	< 2 μm
Grain size after firing on porcelain:	50 μm
Coefficient of thermal expansion:	15,2 $\mu\text{m}/\text{m}\cdot\text{K}$ (25-500 $^{\circ}\text{C}$)

(a) (5)

Since 1988 intensive efforts were made to introduce galvanoforming to crown and bridge technology. These efforts were preceded by studies of the stability under load and the bond strength of galvano-ceramic crowns. Based on a large number of publications, it may be stated that the range of possible indications has been extended considerably from inlays, crowns, partials to bridges, baseplates, biteplates, telescopic and conical crown systems and implant suprastructures. Even the fabrication of bridges in a single-piece galvanoforming technique has been tested.

- (a)(6) Helioform System and Progold Electrocoating System are based on similar technological characteristics.

Differences are as follows:

Progold	Helioform
Using of stone dies excellent bond strength to conventional porcelains	Using of polyurethane dies excellent bond strength and compatibility to conventional porcelains as well as to low firing porcelains with high coefficient of thermal expansion
99,96% electroformed fine gold 16 gold copings in 6-7 hours	99,99% electroformed fine fold 10-20 gold copings in 10 hours
Gold Electrolyte with 15 g/l gold content	Gold Electrolyte with 10 g/l gold content Concentrate with 100 g gold content
recovery capabilities of precious metals from solution	Recovery recommendations of fine gold from Electrolyte
Stone divesting capability	Thermal separation of polyurethane dies

- (b)(1) Numerous in-vitro studies were conducted that looked at fit, marginal leakage, adhesion of bonding materials, stability and fracture resistance as well as on the metal/ceramic interface. What is particularly interesting in this respect is that the marginal fit of Helioform crowns is evaluated as better than those of full ceramic or titanium crowns. Studies of the fracture resistance, too, have shown better results of Helioform crowns than for base metals – including titanium.
- (b)(2) Clinical studies have proved that crown and bridge prosthodontics with or without implants fabricated with the galvanofarming process has enormous advantages over other technologies. The thin gold jacket leaves more space for the ceramic layer which permits a more conservative preparation and thus protects the dental pulp better than an all ceramic or conventional metal ceramic restoration.

(b)(3) Inlays, crowns, and bridges produced by galvanic precipitation of fine gold has become firmly established in dental technology. The advantages are obvious. In the Heliiform procedure 99,99% fine gold is precipitated in the form of a hard, fine-grained structure. By contrast with casting there are no impurities of porosities. Worked procedures at the dental office and at the dental laboratory either remain practically unchanged, or they are even simplified. A high degree of biocompatibility, precision of fit, pulp protection, cementability, esthetics, and reasonable production costs are the most important advantages of galvanofomed restorations.

The Heliiform System is as safe and as effective as the legally marketed Progold Electrocoating System. An advantage of Heliiform precipitations is higher fineness of gold (99,99%) which yields to a better biocompatibility.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 2 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C. Hafner GmbH & Company
C/O Mr. John F. Lemker
Bell, Boyd & Llyod
Three First National Plaza
70 West Madison Street, Suite 3300
Chicago, Illinois 60602-4207

Re: K990670
Trade Name: Helioform Gold-Based Alloy
Regulatory Class: II
Product Code: EJT
Dated: February 26, 1999
Received: March 2, 1999

Dear Mr. Lemker

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 (Pre-market 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

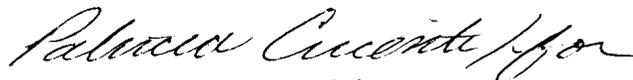
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

K990670



510 (k) Number: K990670

Device Name: Helioform

Indications For Use: Indicated for fixed and removable dental tooth replacement as follows:

- Crowns
- Inlays, Onlays, Overlays, Partial Crowns
- Telescopes, Cones, Overdentures
- Direct Technique
- Double Crown Systems
- Implant Suprastructures
- Bridge Structures
- Baseplates

Detailed descriptions of the above indications can be found in the instructions for Use under 5.1 to 5.7

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use X
 (per 21 CFR 801.109)

Angela Blackwell for MSR
 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
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