



P.O. Box 509 Edenvale 1610
 Republic of South Africa
 Telephone : +27 (11) 609-8640
 Telefax : +27 (11) 452-3918

-14-

K97250

510 (k) Summary

Trade name: HIPALLAUR 19
 Common name: Dental casting alloy
 Classification name: Gold based alloys and precious metal alloys for clinical use
 Classification number: EJT

Legally marketed device: Aurium Aurolite 2A
 Description of the device: Gold reduced palladium based casting alloy
 Intended use of the device: Type IV restoration with porcelain veneering

Summary of the technological characteristics

Test methods applied: as in ANSI/ADA 5 and ISO 9693

Comparison of composition:

ALLOY	Name	COMPOSITION (weight%)							
		Au	Ag	Pd	Sn	In	Fe	Mn	Ru
Legal	Aurolite 2A	13.5	27.8	49.5	4.6	4.4	0	0	x
New	Hipallaur 19	19	10.4	57.1	10.3	2.3	0.3	0.5	0.1

x is less than 1 %

Comparison of physical and mechanical properties

ALLOY	Name	Melting point range (°C)		Hardness (Vickers 5/30)		Yield strength (MPa)		Elongation (%)		CTE (x10 ⁻⁶ /°C)	Density (g/cm ³)
		solid.	liquid	soft	hard	soft	hard	soft	hard		
Legal	Aurolite 2A	1270	1335	170		462		8		14.6	11.7
New	Hipallaur 19	1210	1250	270	370	640	670	20	11	13.7	12.3

Discussion

Both alloys have the same constituents with the exception of two minor ones, i.e. Mn and Fe in Hipallaur 19. Nevertheless, these are oxidized out of the alloy during melting. Hipallaur 19 has a somewhat higher noble metal content (67.1 % vs. 63 %) and less silver and base metals.

Conclusion

On the basis of the constitution the new alloy is very similar to Aurolite 2A, and it may be assumed that due to the higher noble metal content Hipallaur may have slightly better corrosion resistance.





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 1997

Mr. Jerome D. Davis
Managing Director
Aurex Precious Metal Industries..(PTY)..LTD.....
P.O. Box 509
Edenvale 1610
Republic of South Africa

Re: K972950
Trade Name: Hipallaur 19
Regulatory Class: II
Product Code: EJT
Dated: June 13, 1997
Received: June 20, 1997

Dear Mr. Davis:

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.

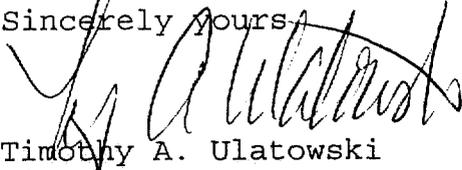
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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

510(k) Number (if known): _____

Device Name: HIPALLAUR 19

Indications For Use:

Dental casting alloy used in combination with dental ceramics for fabrication of metallo-ceramic restoration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Reaver

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

510(k) Number 1697295

Prescription Use
Per 21 CFR 801.109

OR

Over-The-Counter Use _____