

SEP 1997



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-19-

K972955

510 (k) Summary

Trade name: PALCERAM 56
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 IK
Description of the device: Palladium silver 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%)					
		Ag	Pd	Sn	In	Zn	Ru
Legal	Aurolite IK	30	58	6	4	x	x
New	Palceram 56	32	56.5	3.9	7.3	0	0.3

x is less than 1 %

Comparison of physical and mechanical properties

ALLOY	Name	Melting point range (oC)		Hardness (Vickers 5/30)		Yield strength (MPa)		Elongation (%)		CTE (x10-6/oC)	Density (g/cm3)
		solid.	liquid	soft	hard	soft	hard	soft	hard		
Legal	Aurolite IK	1232	1282	260		552		14		14.9	11.3
New	Palceram 56	1200	1230	200	265	470	600	8	3	14.9	11.1

Discussion

The same constituents can be found in both alloys save a minor concentration of Fe vs. Zn.

Conclusion

Identical main elements and the similarity of their content can result in similar chemical and biological effect.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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: K972955
Trade Name: Palceram 56
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.

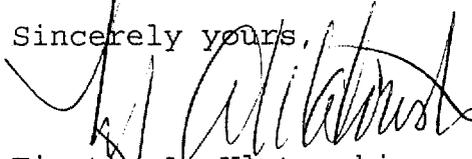
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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: PALCERAM 56

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 Purnas

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972955

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____