JUN 23 2000

K00148

AUREX

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

510 (k) Summary

Trade name:	Palceram 49
Common name:	Dental casting alloy
Classification name:	Gold based alloys and precious metal alloys for clinical use
Classification number:	EJT
Legally marketed device:	Argilite 49 (Argen Corp)
Description of the device:	Palladium – silver based dental 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		COMPOSITION (WEIGHT%)				
	Name	**Pd**	**Ag**	**In**	**Ga**	**Ru**
Legal	Argilite 49	49.5	40.0	9.0	1.0	x
New	Palceram 49	49.0	41.0	8.0	2.0	x

x is less than 1%

Comparison of physical and mechanical properties

ALLOY		Melting point range (°C		Hardness (Vickers 5/30)		Yield strength (Mpa)		Elongation (%)		CTE (x10-6/°C)	Density (g/cm3)
	Name	solid	liquid	hard	soft	hard	soft	hard	soft		
Legal	**Argilite 49**	1150	1246	295	-	660	560	6	-	15.5	10.9
New	**Palceram 49**	1151	1222	290	220	645	460	5	11	14.9	10.6

Discussion

Since the composition of the legally marketed alloy and the new alloy is very similar, it may be assumed that the biological compatibility of the alloys is also very similar.

Conclusion

The main elements and their concentration are almost identical.

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FDA/CDRH/ODE/DHC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2000

Mr. J.D. Davis
Chief Executive Officer
Aurex SA Pty Ltd.
24 Plantation Road, Eastleigh
Edenvale, Gauteng, Rep South Africa 1610

Re: K001481
Trade Name: Palceram 49
Regulatory Class: II
Product Code: EJT
Dated: April 17, 2000
Received: May 11, 2000

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 (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

510(k) Number (if known): K001481

Device Name: Palceram 49

Indications For Use:

Dental casting alloy for metallic restorations in combination with dental porcelains

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runna
(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K001481

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)