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-20-

SEP - 5 1997

K972956

### 510 (k) Summary

Trade name: PALCERAM 82 SF  
 Common name: Dental casting alloy  
 Classification name: Gold based alloys and precious metal alloys for clinical use  
 Classification number: EJT

Legally marketed device: Argen Argipal  
 Description of the device: 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%) |      |     |     |
|-------|---------------|-----------------------|------|-----|-----|
|       |               | Pd                    | Sn   | Ga  | Ru  |
| Legal | Argipal       | 81.5                  | 14.5 | 3.5 | 0.5 |
| New   | Palceram 82SF | 81.6                  | 14.6 | 3.4 | 0.6 |

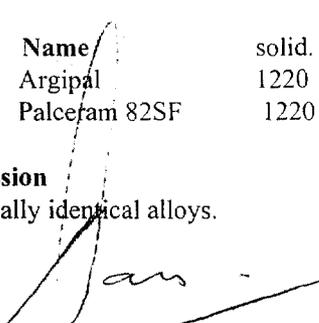
x is less than 1 %

Comparison of physical and mechanical properties

| ALLOY | Name          | Melting point range (°C) |        | Hardness (Vickers 5/30) |      | Yield strength (MPa) |      | Elongation (%) |      | CTE (x10 <sup>-6</sup> /°C) | Density (g/cm <sup>3</sup> ) |
|-------|---------------|--------------------------|--------|-------------------------|------|----------------------|------|----------------|------|-----------------------------|------------------------------|
|       |               | solid.                   | liquid | soft                    | hard | soft                 | hard | soft           | hard |                             |                              |
| Legal | Argipal       | 1220                     | 1250   | 240                     | 245  | 560                  | 660  | 15             | 10   | 14.1                        | 11.2                         |
| New   | Palceram 82SF | 1220                     | 1250   | 230                     | 245  | 560                  | 660  | 15             | 10   | 14.1                        | 11.2                         |

#### Discussion

Practically identical alloys.

Submitted by:  J-D DAVIS

17 June 1997





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: K972956  
Trade Name: Palceram 82SF  
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.

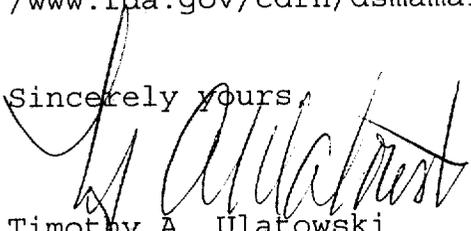
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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: PALCERAM 82SF

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)

*[Handwritten Signature]*

\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K9 2957

Prescription Use  \_\_\_\_\_  
Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_