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-10-

NOV 26 1997

K972945

### 510 (k) Summary

Trade name: AURENORM 68  
 Common name: Dental casting alloy  
 Classification name: Gold based alloys and precious metal alloys for clinical use  
 Classification number: EJT

Legally marketed device: Jelenko Allround 4  
 Description of the device: High gold casting alloy  
 Intended use of the device: Type IV restorations and low fusing porcelain veneering

#### Summary of the technological characteristics

Test methods applied: as in ANSI/ADA 5, ISO 1562 and 9693

Comparison of composition:

ALLOY	Name	COMPOSITION (weight%)							
		Au	Ag	Pt	Cu	Zn	In	Ru	Ir
Legal	Allround 4	69	13.9	9	4.5	2	1.6	0	x
New	Aurenorm 68	68.9	12.1	9.9	6.9	0.9	0.7	0.6	0

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	Allround 4	900	970		260		592		10	16.9	15.8
New	Aurenorm 68	939	977	160	240	410	650	14	8	16.4	16.2

#### Discussion

Both alloys consist of the same major elements. The noble metal content is very high, in excess of 78% and differs only approx. 1 %. The difference in base metal content is even less, i.e. 0.6 %.

#### Conclusion

Basically similar composition and physical, mechanical properties. On the basis of compositional similarity it may be assumed that the biological effect is also similar.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 26 1997

J.D. Davis.  
C.E.O.  
Aurex Precious Metal Industries (PTY) Ltd.  
P.O. Box 509 Edenvale 1610  
Republic of South Africa

Re: K972945  
Trade Name: Aurenorm 68  
Regulatory Class: II  
Product Code: EJS  
Dated: September 16, 1997  
Received: September 30, 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.

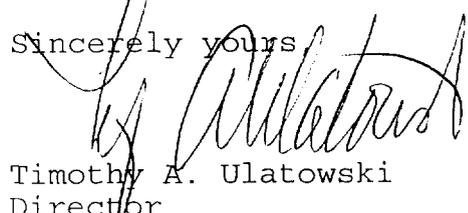
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K972945

Device Name: AURENORM 68

Indications For Use:

Dental Casting alloy used for fabrication of metallo-ceramic restorations in conjunction with dental ceramics of thermal expansion co-efficient not less than  $16.3 \times 10^{-6}/K$ . (25 - 600°C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Kanner*

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

510(k) Number K972945

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)