AUREX
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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
Class ification 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		COMPOSITION (weight%)							
	Name	Au	Ag	Pt	Cu	Zn	In	Ru	Ir
Legal	Allroound 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		Melting point range (°C)		Hardness (Vickers 5/30)		Yield strength (MPa)		Elongation (%)		CTE (x10-6/°C)	Densit (g/cm3)
	Name	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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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 (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 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): 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 x 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)

(Division Sign-Off)
Division of Dental Infection Control,
and General Hospital Devices
510(k) Number K972945

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

(Optional Format 1-2-96)