K021945

SEP - 3 2002

510(K) SUMMARY OF STATEMENT

Submitter of 510(k): Lucius Metals Com.
4241 Farquhar Ave. #2, Los Alamitos, CA 90720
Phone/Fax: (562) 799-6626, Cell: (562) 477-0155

Contact person: Dae Kyu Chang
Phone: (562) 799-6626
Fax: (562) 799-6626
E-mail: Gatorkr@yahoo.co.kr

Date of Summary: June 5, 2002

Trade name: LUCIUS 62
Common: Dental casting alloy
Classification name: Gold based alloys and precious metal alloys for clinical use
Product code: EJT
Classification: Class II

Legally marketed device: Jel-62
510(k) number: K874308

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

Comparison of composition:

	Au(%)	Pt(%)	Pd(%)	Ag(%)	Cu(%)
Jel-62	62.00	0.00	3.00	26.7	9.5
Lucius 62	62.00	0.00	1.500	26.00	8.95

Comparison of physical and mechanical properties:

Alloy	Melting Point Range(°F)	Hardness (Vickers)	Yield Strength (psi)	Elongation (%)	Density (g/cm3)
Jel-62	1,598-1,724	170	42,000	45.0	14.3
Lucius 62	1,652-1,710	150	40,600	33.1	14.1

Discussion:
Since the composition of the legally marketed alloy and the new device 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. LUCIUS 62 is a platinum-free crown and bridge alloy. This device is dependable 62% gold alloy with a high gold appearance. LUCIUS 62 is excellent for inlays, three-quarter crowns, long and short-span bridges. LUCIUS 62 is substantially equivalent to JELENKO'S Jel-62, and the minor differences between them do not affect safety or effectiveness.

Statement of indication for use:
LUCIUS 62 is intended for manufacturing

- Inlay / Onlays
- Crowns
- Short span bridges
- Long span bridges
- Removable partials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2002

Mr. Dae Kyu Chang
President
Lucius Metals Company
4241 Farquhar Avenue, # 2
Los Alamitos, California 90720

Re: K021948
Trade/Device Name: LUCIUS 62
Regulation Number: 872.3060
Regulation Name: Gold-Based Alloys and Precious Metal Alloys for Clinical Use
Regulatory Class: II
Product Code: EJT
Dated: June 5, 2002
Received: June 13, 2002

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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STATEMENT OF INDICATION FOR USE

LUCIUS 62 is intended for manufacturing:

- Inlay / Onlays
- Crowns
- Short span bridges
- Long span bridges
- Removable partials

Susan Runner

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

510(k) Number: K02194