MAR 2 7 2001

K010611

Section E

510(k) SUMMARY

Submitted by:

Jensen Industries
50 Stillman Road
North Haven CT 06473
(203) 239-2090 phone
(203) 239-1015 fax
Contact: John Slanski

Date Prepared: February 26, 2001

Device Name: R&D designation AP-047
Common Name: Dental alloy, precious metal for porcelain-fused-to-metal
Classification: Class II
Product Code: EJT

Predicate Device: V-Gnathos Plus - K952122

Device Description:

AP-047 is a high-noble, gold based alloy suitable for use with the porcelain-fused-to-metal technique of fabricating dental restorations. The physical and mechanical properties of AP-047 make it suitable for cast crowns and fixed partial dentures.

AP-047 is tested to and complies with the International Standard ISO-9693. The corrosion resistance of AP-047 has been tested to and complies with the International Standard ISO 1562:1993(E) Annex A.

Biocompatability of AP-047 has been assesed according to International Standard ISO 10993-1. AP-047 has been tested to and complies with biocompatability tests for cytotoxicity. Sensitization testing according to ISO 10993 is underway, and will be complete prior to marketing.

The safety and effectiveness of AP-047 is therefore determined to be equivalent to the predicate device.

{ref DCF 2235}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2001

Mr. John Slanski
Manager of Research and Development
Jensen Industries, Incorporated
50 Stillman Road
North Haven, Connecticut 06473

Re: K010611
Trade Name: R & D Designation AP-047
Regulatory Class: II
Product Code: EJT
Dated: February 26, 2001
Received: March 1, 2001

Dear Mr. Slanski:

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 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). 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 requirements, 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) 594-4692. 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" (21CFR 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/dsma/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

K010611

Indications for Use Statement

Ver/ 3 - 4/24/96

Applicant: Jensen Industries Incorporated

510(k) Number (if known): K010611

Device Name: R&D designation AP-047

Indications For Use:

AP-047 is a high-noble, gold based alloy suitable for use with the porcelain-fused-to-metal technique of fabricating dental restorations. The physical and mechanical properties of AP-047 make it suitable for cast crowns and fixed partial dentures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010611

{Ref DCF 2235}