

510(k) SUMMARY

DEC 17 1997

**DENTSPLY**

NAME & ADDRESS:

K974035

**DENTSPLY International**  
570 West College Avenue  
P.O. Box 872  
York, PA 17405-0872  
(717) 845-7511  
Fax (717) 854-2343

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: October 22, 1997

TRADE OR PROPRIETARY NAME: 21st CENTURY ALLOY

CLASSIFICATION NAME: 872.3050 - amalgam alloy

PREDICATE DEVICE: Valiant® Amalgam Alloy K801690  
Dispersalloy® Dispersed Phase Alloy Pre-1977

**DEVICE DESCRIPTION AND INTENDED USE:** 21st CENTURY ALLOY is a lathe cut, silver-based dental amalgam alloy designed for stress-bearing Class 1 and Class 2 restorations.

**TECHNOLOGICAL CHARACTERISTICS:** All of the components found in 21st CENTURY ALLOY have been used in legally marketed devices. 21<sup>st</sup> CENTURY ALLOY contains those metallic elements and elemental proportions identical to that commercially used in the past 25 years. Such alloys have historically been proven to be safe and effective as dental restorative materials.

21st CENTURY ALLOY was tested for Acute Oral Toxicity, Mutagenicity, Cytotoxicity, and Pulpal Irritation. All tests showed equivalency to other currently distributed dental amalgam alloy.

We believe that the prior use of the components of 21st CENTURY ALLOY in legally marketed devices, the performance data, and the results of biocompatibility testing support the safety and effectiveness of 21st CENTURY ALLOY for the intended uses.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 17 1997

Mr. P. Jeffery Lehn  
Director, Corporate Compliance and Regulatory Affairs  
DENTSPLY International  
570 West College Avenue  
York, Pennsylvania 17405

Re: K974035  
Trade Name: Century Alloy  
Regulatory Class: II  
Product Code: EJJ  
Dated: October 22, 1997  
Received: October 24, 1997

Dear Mr. Lehn:

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

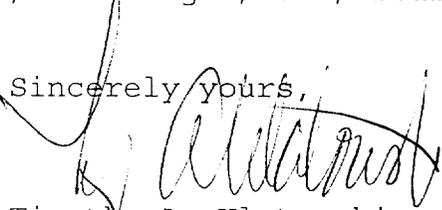
Page 2 - Mr. Lehn

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

**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

(As Required by 21 CFR 801.109)

510(K) Number: K979035

Device Name: 21st CENTURY ALLOY

21<sup>ST</sup> CENTURY ALLOY is a dental alloy designed for stress-bearing  
Class 1 and Class 2 restorations.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

SWAN BUMP  
(Division Sign-Off)

Division of **Dental, Infection Control,**  
and **General Hospital Devices**

510(k) Number K979035

Prescription Use Y OR

Over-The-Counter Use No

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