



OCT 26 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William T. Cousins
Area Manager
Quality Assurance & Regulatory Affairs
Dentsply International
901 West Oakton Street
Des Plaines, Illinois 60018-1884

Re: K994211

Trade/Device Name: AcuCam® Intraoral Camera Sheath
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KXX
Dated: December 1, 1999
Received: December 14, 1999

Dear Mr. Cousins:

This letter corrects our substantially equivalent letter of February 14, 2000 regarding the product code.

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 (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.

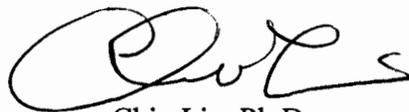
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K994211

FEB 14 2000

**Attachment 11:
510(k) Summary of Safety and Effectiveness
AcuCam® Intraoral Camera Sheath**

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitter: DENTSPLY International, Inc.
Gendex Dental X-ray Division
901 West Oakton Street
Des Plaines, IL 60018-1884

Contact Person: William T. Cousins
Area Manger Quality Assurance & Regulatory Affairs
phone: (847) 640-4924
fax: (847) 640-4970

Date Prepared: December 1, 1999

Device Name: AcuCam® Intraoral Camera Sheath

Common Name: AcuCam Sheath

Classification Name: Dental Operative Device, EIA, 872.6640

Predicate Device: Sanitherm Oral Disposable Thermometer Sheath, 510(k) K983406

Product Description: The AcuCam Intraoral Camera Sheath is a single-use device intended for use with intraoral camera systems. The intraoral camera handpiece is inserted into the sheath prior to use.

Indications for Use: The AcuCam Intraoral Camera Sheath is a single-use device intended for use with intraoral camera systems to prevent contamination of the camera handpiece with saliva and other bodily fluids.

Rationale for Substantial Equivalence

The AcuCam Intraoral Camera Sheath shares the same indications for use as the predicate device. It is manufactured with identical materials, manufacturing process, and inspection and test procedures. The difference between the AcuCam Intraoral Camera Sheath and the predicate device is the size. Biocompatibility of materials has been demonstrated.

Safety and Effectiveness Information:

There are no differences between the design or manufacture of the AcuCam Intraoral Camera Sheath and the predicate device that could affect effectiveness relative to the intended use. Biocompatibility testing was conducted in accordance with ISO 10993-5.

Conclusion:

The AcuCam Intraoral Camera Sheath was found to be substantially equivalent to the predicate device. The AcuCam Intraoral Camera Sheath is substantially equivalent to the predicate device except that the AcuCam Intraoral Camera Sheath is larger in size.

**Section 3:
Intended Use**

510(k) Number (if known): ~~K99424~~ K994211

Device Name: ~~DENTSPLY International, Inc.~~ AcuCam® Intraoral Camera Sheath

Indications for Use: The AcuCam® Intraoral Camera Sheath is a single-use device intended for use with the various intraoral camera systems to prevent contamination of the camera handpiece with saliva and other bodily fluids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use X

(Optional Format 1-2-96)

Chin S. Lim
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994211