

OCT 14 2003

DENTSPLY
GENDEX

K032904

DENTSPLY International
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**510(k) Summary Statement for the
Gendex AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System**

I. General Information

Submitter: DENTSPLY International
Gendex Division
901 West Oakton St.
Des Plaines, IL 60018

Telephone: (847) 640-4800 – Company Number
(847) 640-4924 – Contact Person

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Contact Person: John R. Miller
Director, Quality Assurance and Regulatory Affairs

Summary Preparation Date: September 16, 2003

II. Names

Device Name: AcuCam Concept IV^{FWT} Digital Dental Intraoral
Camera System

Primary Classification Name: EIA – Dental Operative Unit

III. Predicate Devices

- Gendex AcuCam Concept IV Intraoral Camera System
- Vistacam Omni and Vistacam Omni (IC)
- Ultracam

IV. Product Description

The DENTSPLY International, Gendex Division AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System is an imaging device that is intended for use in taking intraoral and extraoral images.

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The DENTSPLY International, Gendex Division AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System is comprised of the following main components:

- Docking station (wall mounted, or counter top)
- Handpiece assembly with monocoil cable

Optional components:

- Video monitor
- Printer

V. Indications for Use / Rationale for Substantial Equivalence

The AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System is an imaging device, which is intended for use by health professionals in taking intraoral and extraoral images of dental anatomy in order to:

1. To assist the dental practitioner in the assessment of the overall dental health of the patient by providing high quality, magnified images of regions of the oral cavity which otherwise are difficult or impossible to view.
2. Allow the dental practitioner to provide educational information to the patient and to more effectively communicate a treatment plan.
3. Provide documented images for patient records, insurance companies, and health professionals.
4. To allow the practitioner to provide before and after color images showing the results of the dental procedures performed.

The end user must insure that any peripheral equipment (i.e., monitor, printer, computer, etc.) used with the AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System is approved for medical applications under the respective national regulations.

It shares the same indications for use, similar materials, design, operational, and functional features and therefore is substantially equivalent to the predicate devices listed in Section III of this summary.

VI. Safety and Effectiveness Information

Safety and Effectiveness is demonstrated by:

- Performance testing to meet product/specifications
- Software testing to validate software design / performance
- Effective clinical image exposures
- Hazard analysis including risk level and solution
- Same indications for use as predicate devices.

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All the aforementioned steps and evaluations combine to demonstrate that the AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System is safe and effective when the device is used as labeled.

VII. Conclusion

The AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System was found to be Substantially Equivalent to the predicate devices; the Gendex AcuCam Concept IV, the Air Techniques Vistacam Omni and Vistacam Omni (IC), and Mr. W. Edward Johansen's Ultracam. The AcuCam Concept IV^{FWT} Digital Dental Intraoral Camera System shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices. It has been shown to be safe and effective when used as labeled.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 2003

Mr. John R. Miller
Director
Quality Assurance and Regulatory Affairs
Dentsply International
901 West Oakton Street
Des Plaines, Illinois 60018-1884

Re: K032904

Trade/Device Name: AcuCam Concept IV^{FWT} Digital Intraoral Camera System
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: September 16, 2003
Received: September 25, 2003

Dear Mr. Miller:

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.

Page 2 –Mr. Miller

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), please contact the Office of Compliance at (301) 594-4613. 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

510(k) Number (if known): Not Assigned

Device Name: AcuCам Concept IV^{FWT} Digital Dental Intraoral Camera System

Indications for Use:

The AcuCам Concept IV^{FWT} Digital Dental Intraoral Camera System is a dental imaging system intended for use by health professionals in taking intraoral and extraoral images of dental anatomy.

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032904

Prescription Use (Per 21CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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