4/29/99

K984332

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25 November 1998

510(k) Summary as required by section 807.92(c)

Submitted by the contact person:

Austin Brewin, M.D.
Piedmont Consulting Group
6114 LaSalle Avenue, Oakland, CA 94611
Phone, Fax: 510-547-1211

- The Device:

  Trade Name: SpectraVu Family of Intraoral Camera Systems manufactured and marketed by International Technology Concepts (ITC/SpectraVu) of 11501 Dublin Boulevard, Dublin, CA 94568. Phone: 800-549-2727 Fax: 408-395-1490

  Common Name: Intraoral video camera

  Classification Name: Dental Operative Unit and Accessories (76 EIA)

- Equivalent legally marketed device:

  Ultracam II, made by Ultrac, Inc, a division of Dental Vision Direct, Inc. The 510(k) number assigned for this equivalent system is K941452.

- Summary of technological similarities between the SpectraVu and UltraCam systems:

Feature:	SpectraVu	UltraCam
Used for dental patient education	Yes	Yes
General dental office use	Yes	Yes
Ergonomic, portable design	Yes	Yes
Portable and fixed models	Yes	Yes
Built-in back-up battery	Yes	Yes
Accurate optical lens system	Yes	Yes
Variable focal lengths	Yes	Yes
Integrated camera-light cable	Yes	Yes
Digital, on-board image storage	Yes	Yes
High resolution image	Yes	Yes
Accurate color image	Yes	Yes
Display single or multiple images	Yes	Yes
Computer or S-Video output	Yes	Yes
On the unit control	Yes	Yes
Handpiece image capture control	Yes	Yes
Autoclavable window sleeves	Yes	No
EMC approved	Yes	UL Approved

- Summary Description of the Device: The SpectraVu Family of Intraoral Camera Systems consist of a power supply, digital camera processor, circuit boards, a light source, optical and electronic cables, and an ergonomic hand piece with an autoclavable sleeve containing an optical system. The components are capable of capturing images over a wide focal range. The images can be displayed on a television monitor, in a computer or may be printed out.
- Intended use of the device: Intraoral images captured and displayed by the cameras are intended to be used to aid in patient education, enhancement of defect detection, and for image storage. These are not intended to aid in dental surgical procedures.

- The SpectraVu Family of Intraoral Camera Systems provides intraoral images, and are not substantially different from currently marketed devices such as the UltraCam systems.

Respectfully submitted,

A Brewin

Austin Brewin, M.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

International Technology Concepts
C/O Austin W. Brewin, M.D.
Piedmont Consulting Group
6114 LaSalle Avenue, Suite 330
Oakland, California 94611

Re: K984332
Trade Name: Spectra Vu 1000 Series Intraoral Camera, Spectra Vu 2000 Series
Regulatory Class: I
Product Code: EIA
Dated: March 15, 1999
Received: March 23, 1999

Dear Dr. Brewin:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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

510(k) Number K 984332

13. Statement of indications for use:

The SpectraVu Family of Intraoral Cameras are intended for use in dentistry to provide a view of the oral cavity and contents as an aid in explaining and demonstrating conditions to patients. These also provide an enlarged view of areas for the dentist to better identify defects. Images can be stored for future reference.

These cameras are not intended for use as an operative device. The camera and components are not manufactured to be sterile, however the metallic sleeve tip with the glass optical window is designed to be sterilized between uses, and/or may be protected by commercially available plastic disposable sleeves.

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984332

PRESCRIPTION DEVICE
(Rx)