K013690

SECTION 9 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 3 0 2002

This 510(k) summary of safetly and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92(c).

Submitter: Confident Technology Inc.
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Date Prepared: 10/30/2001

Trade / Proprietary Name: iDENT-A100 Intraoral Video Camera

Common/Usual Names: Intraoral video camera

Classification Names: Dental Operative Unit and Accessories (76 EIA)
Class I

Description of the Device:

The iDENT-A100 Intraoral Video Camera provides clear, high resolution images of the oral cavity, which can be stored and manipulated in the built digital memory and used for visual communication directly to the patient. The System can capture one full image or can capture four images into one frame and the captured images can be display on a video monitor. The operation of the capturing image can be done by a foot switch or a push button and is very user-friendly. The typical dentist and assistant can use the system with a few minutes training.

A high resolution, true color image is produced on the screen by a rod lens scope design which is the standard in the industry for endoscopic procedures. There is no peripheral distortion of the image. Manual focusing is not required and a single tooth or full arch view can be captured without changing the scope. The unit is easily detached for autoclaving cleaning.

Indications for use:

The iDENT-A100 Intraoral Video Camera of the Confident Technology Inc. is used to provide a view of the mouth in order to assist the dentist in describing dental

procedures and to show a patient before and after views of his/her mouth showing the patient results of the dental procedures which the dentist has performed on him/her. These are not intended to aid in dental surgical procedures.

Predicate Device:

W. EDWARD JOHANSEN's ULTRACAM cleared under 510(k) K973410 on 10/08/1998 and AIR TECHNIQUES, INC.'s VISTACAM OMNI AND VIASTCAM OMNI (IC) cleared under 510(k) K974204 on 01/08/1998.

Rationale for Substantial Equivalence:

The iDENT-A100 Intraoral Video Camera shares the same indications for use as the predicate devices. Since the design is comparable, technology virtually identical, the specifications very similar.

Conclusion:

Based on the supportive documentation and descriptions outlined in this premarket notifications-510 (k), we believe that the iDENT-A100 Intraoral video camera is substantially equivalent to those of similar types of products, used for parallel purposes, currently on the market. The iDENT-A100 Intraoral Video Camera was found to be substantially equivalent to the predicate devices.

End of Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Mr. Lewis Lin
President
Confident Technology, Incorporated
13841 Roswell Avenue #K
Chino, California 91710

Re: K013690
Trade/Device Name: iDENT-A100 Intraoral Video Camera
Regulation Number: 872.6640
Regulation Name: Intraoral Video Camera
Regulatory Class: I
Product Code: EIA
Dated: October 31, 2001
Received: November 7, 2001

Dear Mr. Lin:

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.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

K013690

510(k) Number : To Be Assigned By FDA

Device Name: iDENT-A100 Intraoral video camera

Indication for Use:

The iDENT-A100 Intraoral video camera of the Confident Technology Inc. is used to provide a view of the mouth in order to assist the dentist in describing dental procedures and to show a patient before and after views of his/her mouth showing the patient results of the dental procedures which the dentist has performed on him/her.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013690

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.109)