K040691

510(k) Summary

MAR 2 3 2004

As Required by 21 section 807.92 (c)

1-Submitter Name: WIN-US TECHNOLOGY CO., LTD
2-Address: 3F Younbg-Pung B/D, #225-1 Poi-Dong
Kangnam-Ku, Seoul, Korea
3-Phone: 82-2-529-3785
4-Fax: 82-2-572-3784
5-Contact Person: (on behalf of the submitter) Jay Mansour, Mansour Consulting LLC 1308 Morningside Park Dr Alpharetta, GA 30022 USA (770) 777-4146 Fax (678) 623-3765
6-Date summary prepared: January 9th, 2004
7-Device Trade or Proprietary Name: Win-100D
8-Device Common or usual name: Intra Oral Camera system and accessories
9-Device Classification Name: Unit, Operative, Dental
10-Substantial Equivalency is claimed against the following device:

- DIGITAL DOC from Digital Doc, Inc.
  510k # K981663

11-Description of the Device: **(For technical specifications, refer to the user manual)**
(Full listing and photos of accessories is available within this submission- refer to User Manual)

Our device comprises of a light (0.6Kg), small (230mmX12mm), compact design and ergonomic handpiece along with a multi-docking system.

The handpiece consists of a focusing mechanism and a capture button to assist the doctor in taking intraoral or full face images of the patient.

The handpiece connects to a multi-docking system via a cable.

The multi-docking system in turn can connect directly to a monitor and PC via a standard composite connection (RCA).

It uses high definition imaging (460 TV-lines) to capture images at 80 degrees field of view.

It can make the screen in 4 frames or full screen mode via a multi-docking system. It can change the side of the captured image.

12-Intended use of the device: (refer to FDA form attached)

Win-100D intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above. This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. **Refer to the detailed explanations within the main submission.**

FDA file reference number	510k # K981663
Attachments inside notification submission file	510k FDA website print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Not Applicable
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 2004

Win-US Technology Company Limited
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01719

Re: K040691
Trade/Device Name: Intra-Oral Camera System and Accessories, WIN-100D
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: March 16, 2004
Received: March 17, 2004

Dear Mr. Lehtonen:

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.

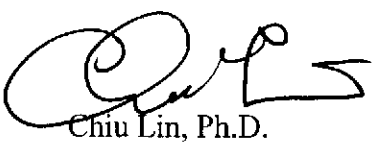
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-5613. 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

Indications for Use

510(k) Number (if known): K040691

Device Name: Intra-Oral Camera System and Accessories, WIN-100D

Indications For Use:

Win-100D intra oral camera system and accessories is indicated for use to provide the dentist and the patient with a view of the mouth before and after the dental procedure, which assists the dentist in describing the dental procedure being performed as well as showing the results.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 Anesthesiology, General Hospital,
Infection Control, Dental Devices

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