K111771

NOV 3 0 2011

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

2.1. General Information Establishment

- Manufacturer: **United Integrated Service Co., Ltd.**
- Address: 5F, No. 3, Lane 7, PaoKao Road, Hsintein, New Taipei City, 23144, Taiwan
- Owner Number: **9049882**
- Contact Person: Dr. Jen, Ke-Min E-mail: ceirs.jen@msa.hinet.net
  886-3-5208829 (Tel); 886-3-5209783 (Fax)
  Address: No.58, Fu Chiun Street, Hsin Chu City, 30067, Taiwan, ROC
- Date Prepared: June 18, 2011

Device

- **Proprietary Name:** *United Integrated Non-Contact Thermograph System*
  Model: *IT-85*
- **Common Name:** Opthalmic Camera
- **Classification Name:** Camera, Ophthalmic, Ac-Powered, Class II
- **Product Code:** HKI

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to LipView Ocular Surface Interferometer **(K091935)**
- **Device Description:** The ocular surface temperature is measured by the thermal sensor of the thermograph system. The subject places his/her chin and forehead to the measuring bracket. Keep both eyes on the camera of the thermograph system. Listen to the voice instruction to close and open his/her eyes for recording the temperature variation of his/her ocular surface.
- **Intended Use:**
  The UIS Non-Contact Thermograph System is an ophthalmic imaging device that stores, archives, and manipulates digital images of ocular surface temperature measurements taken by a physician in adult patients.
- **Substantial Equivalence (SE)**
  A claim of substantial equivalence is made to LipView Ocular Surface Interferometer **(K091935).** Both of them have the similar working principle and technologies. The major differences for the two devices are the subject device is controlled by the keypad buttons or keyboard, and mouse user control; and the predicate device is touch screen user control. Especially, the real-time dynamics of the subject device is based on thermal pattern from the direct radiation of

ocular surface, thus it has no illumination source; but the predicate device is based on interference pattern from specular reflection which has the angled class I white LEDs with diffuser to illuminate lower half of eye. The differences are due to the feature design aspects, not relating to the safety or effectiveness aspects. They are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

United Integrated Service Co., Ltd.
c/o Dr. Ke-Min Jen
Official Correspondent
No. 58, Fu Chiun Street
Hsin Chu City, TW-HSQ
China (Taiwan) 30067

NOV 3 0 2011

Re: K111771
Trade/Device Name: Non-Contact Thermograph System, IT-85
Regulation Number: 21 CFR 886.1120
Regulation Name: Camera, ophthalmic, AC-powered
Regulatory Class: Class II
Product Code: HKI
Dated: November 2, 2011
Received: November 16, 2011

Dear Dr. Jen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K111771

Device Name: *Non-Contact Thermograph System, IT-85*

Indications for Use:

The UIS Non-Contact Thermograph System is an ophthalmic imaging device that stores, archives, and manipulates digital images of ocular surface temperature measurements taken by a physician in adult patients.

Prescription Use √ AND/OR Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(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 Ophthalmic, Neurological and ear,
Nose and Throat Devices

510(k) K111771