OCT 18 2011

Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: July 26, 2011

2. Sponsor

Visiomed Group SA
21, avenue Victor Huge, 75116, Paris, France

Establishment Registration Number: Not yet registered

Contact Person: Mr. Eric Sebban
Position: President
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3. Proposed Device Identification

Proposed Device Name: ThermoFlash™ Infrared Thermometer
Proposed Device Model: LX-26, LX-261, LX-260 and LX-260T

Classification: Class II
Product Code: FLL
Regulation Number: 21 CFR 880.2910
Review Panel: General Hospital

Intended Use Statement:
ThermoFlash™ is an infrared thermometer for body surface and forehead temperature measurement for infants and adults without contacting to human body. It can be used by consumers in household environment and doctor in clinic as reference.

4. Predicate Device Identification

510(k) Number: K090361
Product Name: Remote Infrared Thermometer, RC002
Manufacturer: Rycom Electron Technology Limited

5. Device Description

ThermoFlash™, including LX-26, LX-261, LX-260 and LX-260T, are handheld electronic thermometer that measures the body temperature based on the infrared sensor technology.

All objects emit energy by radiation. The intensity of this energy depends on the temperature of the object. ThermoFlash™ is, therefore, able to measure the temperature of a person by the energy the person emits. Infrared sensor can sense the infrared emissions from the human body (forehead) and environment; then the electronic signal will be transferred by AD module to the digital signal and displayed on the LCD screen.

- LX-26 is a thermometer with basic temperature measurement functions.
- LX-260 is an advanced model to LX-26, which provides three additional keys which allow user to select the measurement directly;
- LX-261 is an advanced model to LX-260, which provides a rechargeable station base and inner Li rechargeable battery which can be recharged;
- LX-260T is an advanced model, which provides voice indicating of measured temperature.

6. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995. (General);
- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests +Amendment 1: 2004;
- ASTM E1965-98 (R2009): Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature. (General Plastic Surgery/General Hospital).

7. Substantially Equivalent Conclusion

Compared with the predicate device, ThermoFlash™ Infrared Thermometers have some additional features of voice indicator and rechargeable battery, and different specifications of power supply. Based the on the comparison and analysis in Section 7 Substantially Discussion, these differences were determined not to affect the performance and effectiveness.

The proposed device, ThermoFlash™ Infrared Thermometer, is determined to be Substantially Equivalent (SE) to the predicate device, Remote Infrared Thermometer, RC002, K090361 in respect of safety and effectiveness.

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

OCT 18 2011

Visiomed Group SA
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607

Re: K112929
Trade/Device Name: ThermoFlash™ Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: September 21, 2011
Received: October 3, 2011

Dear Mr. Mouser:

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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section II Indications for Use

510(k) Number:
Device Name: ThermoFlash™ Infrared Thermometer
Models: LX-26, LX-261, LX-260 and LX-260T

Indications for Use:

ThermoFlash™ is an infrared thermometer for body surface and forehead temperature measurement for infants and adults without contacting to human body. It can be used by consumers in household environment and doctor in clinic as reference.

☐ PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒ OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112929