K101322

EXHIBIT #1

510(k) Summary

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

Date prepared: May 5, 2010.

1. **Applicant:**
   Joinsoon Electronics MFG. Co., Ltd.
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   Taiwan, R.O.C.
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   JUL 2 8 2010

2. **Submitter:**
   Mr. Jigar Shah
   Official Correspondent for
   Joinsoon Electronics MFG. Co., Ltd.
   mdi Consultants, Inc.
   55 Northern Blvd., Suite 200
   Great Neck, New York 11021
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   Jigar@mdiconsultants.com

3. **Trade/proprietary Name:**
   Joinsoon Electronics Mfg. Co., Ltd. Infrared Ear Thermometer, Model TT-001

4. **Classification name:**
   Common Name: Clinical Electronic Thermometer
   Regulation: 21 CFR Part 880.2910

5. **Product Code:**
   FLL

6. **Predicate Devices:**
   TempTeller – Infrared Ear Thermometer, Models CT-31/32DX/32/32DX
   Cleared 510(k) number: K030299

7. **Device Description**

   The device TT-001 is an electronic thermometer using an infrared sensor to detect body temperature from the auditory canal. Its operation is based in the measuring the natural thermalradiation emanating from the tympanic membrane and the adjacent tissue.

   The tympanic membrane (eardrum) is thin and flooded with blood at the core temperature. The waveguide, usually a cylindrical pipe with a highly reflective inner surface for confining the radiation, is adaptive to the outer without

contacting the eardrum. When inserting the probe into the ear canal, the radiation fluxes transfer among the tympanum membrane (eardrum), the IR sensor, and the inner surface of the waveguide. The ambient sensor is packed with the IR sensor to monitor the ambient temperature of the IR sensor.

To measure core temperature, an ear thermometer is inserted into a patient's outer ear canal. An activation button is pressed to start the measurement through the radiation exchanges. The electrical signal readouts form the IR sensor and the ambient temperature sensor are fed to the circuit for amplification, digitization and calculation. The measured temperature then appears on the LCD. The total operation takes one second.

The Fundamental Scientific technology of the modified device remains the same as that of the 510(k) cleared device.

8. **Intended Use:**
The device is a clinical electronic thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

9. **Substantial Equivalence Discussion:**
The Joinsoon Electronics MFG. Co., Ltd. High Speed Digital Thermometer Model TT-001 is substantially equivalent to the original 510(K) 030299, Model CT-32DX in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc.,

The only differences in the predicate version of the Digital thermometer are PCB layout involving Performance Specifications and Housing for Ergonomics of the Patient-UI.

The Fundamental Scientific technology of the modified device remains the same as that of the 510(k) cleared device.

10. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Compliance to applicable voluntary standards includes ASTM E1965-98, as well as IEC60601-1 and IEC60601-1-2 requirements.

Guidance documents included the "FDA Guidance on the content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

11. **Conclusion:**
The Joinsoon Electronics MFG. Co., Ltd. High Speed Digital Thermometer Model TT-001 has the same intended use and similar technological characteristics as the Predicate device. Moreover, bench testing contained in this submission supplied demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus the Joinsoon Electronics MFG. Co., Ltd. High Speed Digital Thermometer Model TT-001, is substantially equivalent to the predicate device.

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

Joinsoon Electronics Manufacturing Company Limited
C/O Mr. Jigar Shah
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

JUL 28 2010

Re: K101322
Trade/ Device Name: Infrared Ear Thermometer, Model TT-001
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 24, 2010
Received: June 28, 2010

Dear Mr. Shah:

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 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

EXHIBIT#3

Indications for Use

510(k) Number (if known):

JUL 2 8 2010

Unknown at this time

K101322

Device Name:

Joinsoon Electronics Mfg. Co., Ltd. Infrared Ear Thermometer. Model TT-001

Indications for Use:

The device is a clinical electronic thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(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)

7/28/10

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

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