DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 20, 2016

ARC Devices Limited
Mr. Gary Brogan
Director of Quality and Regulatory Affairs
2 Deerpark Industrial Estate
Oranmore, Co. Galway
Ireland

Re: K152905
Trade/Device Name: ARC InstaTemp™ Non-touch Thermometer, ARC InstaTemp™ MD Non-touch Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: June 10, 2016
Received: June 16, 2016

Dear Mr. Brogan:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152905

Device Name
ARC InstaTemp™ Non-Touch Thermometer

Indications for Use *(Describe)*

The ARC InstaTemp™ is an infrared thermometer that measures temperature from the forehead in both infants and adults without contacting the human body.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152905

Device Name
ARC InstaTemp MD™ Non-Touch Thermometer

Indications for Use *(Describe)*

The ARC InstaTemp MD™ is an infrared thermometer that measures temperature from the forehead in both infants and adults without contacting the human body. It is intended for use by a Health Care Professional in a clinical environment. This device is not intended for home use.

Type of Use *(Select one or both,* as *applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary (21 CFR 807.92)
K152905

I. SUBMITTER

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Contact Person:
Gary Brogan
Director or Quality and Regulatory Affairs,

Date Prepared: July 20, 2016

II. DEVICE

Name of Devices: ARC InstaTemp™ Non-Touch Thermometer
ARC InstaTemp MD™ Non-Touch Thermometer

Common or Usual Name: Infrared Thermometer

Classification Name:
21 CFR 880.2910 (Clinical Electronic Thermometer)

Regulatory Class: Class II

Product Code: FLL

III. PREDICATE DEVICE

Rycom Electron Technology Limited, *RC002 Remote Infrared Thermometer,* K090361, cleared 16th June 2010.

IV. DEVICE DESCRIPTION

The ARC Non-Touch Thermometer is a fast, accurate and non-intrusive device for measuring a person's temperature. It uses infrared sensor technology to detect the radiated infrared energy emitted from the forehead. Therefore as soon as the sensor is held near the forehead and activated, the temperature measurement is taken by detection of the emitted infrared heat generated by the arterial blood flow.
The ARC Non-Touch Thermometer uses sensor technology that detects the emitted heat from

the temporal artery in the forehead from a distance of approximately 1 inch. Once recorded an internal algorithm converts this forehead surface temperature into human body temperature and it is this temperature that is then presented to the user on the LCD screen. This temporal artery detection mechanism and the resulting conversion to body temperature characterizes the ARC Non-Touch Thermometers as an adjusted mode clinical thermometer as per ISO 80601-2-56. This is the same principle of operation as the listed predicate device, K090361.

The ARC Non-Touch Thermometer is indicated for the measurement and display of human body temperature for patients of all ages. It can be used by responsible adults at home or by health care professionals in a clinical environment. In order to serve both these markets, ARC Devices have developed two separate models, the *ARC InstaTemp™ Non-Touch Thermometer* for home use and the *ARC InstaTemp MD™ Non-Touch Thermometer* for professional use. Both models have the same purpose, design, materials, energy source and function and also possess the same features related to safety and effectiveness. It is for this reason that the two models are included in the one 510k pre-market submission. This is in compliance with, *Guidance for Industry and FDA Staff, Bundling Multiple Device or Multiple Indications in a Single Submission, June 22, 2007.* The differences between both models while minor in nature and have been introduced to make the device more suitable for professional use as opposed to home use.

V. INDICATIONS FOR USE

The ARC InstaTemp™ is an infrared thermometer that measures temperature from the forehead in both infants and adults without contacting the human body.

The ARC InstaTemp MD™ is an infrared thermometer that measures temperature from the forehead in both infants and adults without contacting the human body. It is intended for use by a Health Care Professional in a clinical environment. This device is not intended for home use.

The ARC InstaTemp™ and InstaTemp MD™ devices intentions for use are different from the predicate intentions for use statement because the user environments are specific to either home use or clinical use, whereas the predicate device can be used in either home use or clinical use. This difference does not raise new questions regarding safety and effectiveness because the technology is similar, the bodily measurement site is identical, and the user environments are the same but limited to specific devices.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Parameter	RC002 Remote Infrared Thermometer	ARC InstaTemp™ Non-Touch Thermometer	ARC InstaTemp MD™ Non-Touch Thermometer	Comparison
Measurement Method	RC002 Remote Infrared Thermometer uses an infrared sensor to detect and record the emitted heat from the temporal artery in the forehead. In the 'body' function it converts this forehead surface temperature into body temperature and it is this temperature that is then presented to the user on the LCD screen.	ARC InstaTemp™ Non-Touch Thermometer uses an infrared sensor to detect and record the emitted heat from the temporal artery in the forehead. It then converts this forehead surface temperature into human body temperature and it is this temperature that is then presented to the user on the LCD screen.	ARC InstaTemp MD™ Non-Touch Thermometer uses an infrared sensor to detect and record the emitted heat from the temporal artery in the forehead. It then converts this forehead surface temperature into human body temperature and it is this temperature that is then presented to the user on the LCD screen.	Same
Range	In Body Mode: 32-42.9^{0}C	32-42.8^{0}C	32-42.8^{0}C	Same
Parameter	**RC002 Remote Infrared Thermometer**	**ARC InstaTemp™ Non-Touch Thermometer**	**ARC InstaTemp MD™ Non-Touch Thermometer**	**Comparison**
Accuracy	$\pm$ 0.3^{0}C	$\pm$ 0.2^{0}C	$\pm$ 0.2^{0}C	Verified by compliance testing to IEC 60601-1.
Precision	$\pm$ 0.3^{0}C (34-35.9^{0}C) $\pm$ 0.2^{0}C (36-39^{0}C) $\pm$ 0.3^{0}C (39-42.5^{0}C)	$\pm$ 0.2^{0}C	$\pm$ 0.2^{0}C	Verified by compliance testing to IEC 60601-1.
Measurement Distance	5-8cm	1-3cm	1-3cm	Acceptable
Power supply	2 x AA Battery	2 x AAAA Battery	2 x AAAA Battery	Acceptable
Operating	10^{0}C to 40^{0}C	10^{0}C to 40^{0}C	10^{0}C to 40^{0}C	Same
Display	LCD	LCD	LCD	Same
Display	0.1^{0}C	0.1^{0}C	0.1^{0}C	Same
Celsius / Fahrenheit	Yes	Yes	Yes	Same
Led Backlight	Yes	Yes	Yes	Same
Automatic Stop	5 seconds	4 $\pm$ 0.5 seconds	4 $\pm$ 0.5 seconds	Same
Dimensions	196x150x50mm (LxWxH)	129x35x13mm (LxWxH)	129x35x13mm (LxWxH)	Acceptable

The following technological differences exist for the ARC Non-Touch Thermometers and its predicate device.

- The accuracy and precision is 0.2^{0}C across the full range as opposed to 0.3^{0}C for the predicate - This was verified during compliance testing to IEC 60601-1
- The size of the battery used to power the device - The batteries were verified as being acceptable as part fulfillment of compliance testing to IEC 60601-1.

- The recommended measurement distance – Reduction of the measurement distance reduces the noise due to ambient temperature. 1-3cm is a comfortable distance for the user to operate these thermometers.
- Dimensions of the devices – The changes in dimensions have no effect on functionality of the thermometer. The modified dimensions are deemed acceptable as the unit can be used by a single operator in the same way as the predicate.

Upon review of these technological differences, it can be concluded that they do not affect the core function of the device. In addition as both the subject and the predicate devices meet the same FDA recognized consensus standards, it can be concluded that the subject devices are substantially equivalent to the predicate device.

VII. COMPARISON OF MATERIALS USED WITH THE PREDICATE DEVICE

RC002 Remote Infrared Thermometer	**ARC InstaTemp™ Non-Touch Thermometer**	**ARC InstaTemp MD™ Non-Touch Thermometer**
Materials of Components in contact with the operators hand: *Acrylonitrile butadiene styrene (ABS)*	*Materials of Components in contact with the operators hand:* Upper Housing – Polycarbonate Lower Housing – Polycarbonate Button – Polycarbonate LCD Screen - Polycarbonate	*Materials of Components in contact with the operators hand:* Upper Housing – Polycarbonate Lower Housing – Polycarbonate Button – Polycarbonate LCD Screen - Polycarbonate

As can be reviewed in the table, the material in contact with the operators hand is ABS in the predicate device while it is Polycarbonate in the ARC Non-Touch Thermometer. The contact duration throughout the lifetime of the device would be <24hours and the device would always be in contact with intact skin.

Both ABS and Polycarbonate are used widespread in the medical device field and neither have any concerns from a user safety viewpoint. In addition the material does not affect the performance of the device. That aside biocompatibility testing, per ISO 10993-5:2009 and ISO 10993-10:2010 has been completed on both the ARC InstaTemp™ and the ARC InstaTemp MD™ to demonstrate that no biocompatibility concerns exist that affect the substantial equivalence claim.

VIII.BIOCOMPATIBILITY

The ARC Non-Touch Thermometer is manufactured from an outer casing of polycarbonate that comes into direct contact with the operator's hand. For this reason, and in order to maintain compliance to ASTM E1965, GLP Biocompatibility testing in compliance to ISO 10993-5:2009 (cytotoxicity analysis) and ISO 10993-10:2010 (skin irritation analysis) was carried out on both the ARC InstaTemp™ and the ARC InstaTemp MD™. This testing concluded that no biocompatibility issues exist with the ARC Non-Touch Thermometer.

IX. NON-CLINICAL PERFORMANCE DATA

The following non-clinical performance data was provided in support of the substantial equivalence determination:

Software Verification and validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDAs Guidance for Industry and FDA Staff 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'. The software for this device was considered as a 'moderate' level of concern since a malfunction of, or a latent design flaw in, the software device could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to minor injury.

Electrical Safety and Electromagnetic Compatibility (EMC)
Electrical safety and EMC testing was conducted for the ARC Non-Touch Thermometer. This testing concluded that the device is in compliance with IEC 60601-1, IEC 60601-1-11 (2010) and ISO80601-2-56 standards for safety and IEC 60601-1-2 standard for EMC.
Bench Performance Testing
The following bench testing was performed to support substantial equivalence

- ASTM E1965-98 (Reapproved 2009), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
- Software / Algorithm report / Comparison Report with an identical device to the predicate.

X. CLINICAL PERFORMANCE DATA

A clinical trial was completed on 136 subjects which verified the clinical performance by way of a clinical accuracy validation as defined in ISO 80601-2-56, section 201.102. The test report concluded that based on the required sample sizes as mandated by the standard that the ARC Devices Non-Touch Thermometer has levels of reproducibility and accuracy, for both febrile and non-febrile patients that are in keeping with the existing devices that are in widespread hospital practice. This clinical trial demonstrates that the ARC Devices Thermometer performs in the clinical setting and so substantial equivalence can be drawn to the predicate.

XI. CONCLUSIONS

The ARC Non-Touch Thermometer, has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety through the successful testing to IEC 60601-1, IEC 60601-1-11 (2010) and ISO80601-2-56 along with successful testing to the electromagnetic standard IEC 60601-1-2. Furthermore, the subject device also meets the specific requirements of ASTM E1965-98.

Taking this information into account, it is concluded that the ARC Non-Touch Thermometer which includes both the ARC InstaTemp™ Non-Touch Thermometer and the ARC InstaTemp MD™ Non-Touch Thermometer, are substantially equivalent to the predicate device, the RC002 Remote Infrared Thermometer (K090361)