DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2017

Easywell Biomedicals, Inc.
Arthur Chen
Quality Assurance Manager
Suite 2, 2F, No.9, Jhanye 1st Rd, Hsinchu Science Park
Hsinchu, 30078
TAIWAN

Re: K162509
Trade/Device Name: Infrared Non-contact Thermometer, Model ACT8100
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: January 26, 2017
Received: February 15, 2017

Dear Arthur Chen:

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,

Tina Kiang
-S

Tina Kiang, Ph.D.
Acting 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)*
K162509

Device Name
Infrared Non-Contact Thermometer, Model ACT8100

Indications for Use *(Describe)*
The Infrared Non-Contact Thermometers, ACT8100, is non-sterile, reusable clinical thermometers intended for the intermittent determination of human body temperature measured at the center of the forehead without contact. The device is intended for use on people of all ages, except pre-term babies or very small (small for gestational age). The device is intended for use in clinical and home use environments.

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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K162509
510(k) Summary

I. Submitter

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Date: January 25, 2017

II. Device

Trade Name：Infrared Non-Contact Thermometer, Model ACT8100

Common Name: Infrared Thermometer

Regulation Number: 21 CFR 880.2910

Regulation Name：Clinical Electronic Thermometer

Regulatory Class：Ⅱ

Product Code：FLL

III. Predicate Device

K134043：BRAUN No Touch + Forehead Thermometer; ModelNTF3000US (US Model)

Reference Device

K031905: Actherm Digital Clinical Thermometer ACT 2130

IV. Device Description

The Infrared Non-Contact Thermometer, ACT8100 is a hand-held device powered by batteries and designed to measure human body temperature without contacting patients. This thermometer can switch modes between forehead and ambient temperatures. The ambient temperature mode is DIRECT MODE and the forehead temperature mode is ADJUSTED MODE. The forehead temperature of the ADJUSTED MODE is calculated by converting the measured temperature of the DIRECT MODE to an oral equivalent temperature without contacting the patient's forehead. Infrared Non-Contact Thermometer, ACT8100 uses a thermopile integrated with a thermistor, a thermistor mounted on the head of the thermometer for ambient temperature readings, and an optoelectronic mechanism that focuses the infrared energy emitted from the user's forehead for the detection of non-contact use and calibration of temperature reading.

Physical and Performance characteristics:

Dimension	163×44×26mm approximately
Weight	Approximately 75g without battery; 88g with batteries
Measuring Range	32.0 °C ~ 43.9 °C (89.6 °F ~ 111.0 °F)
Accuracy	± 0.2 °C (for 35.0~42.0°C); ± 0.3°C (for below 34.9°C or above 42.1°C)

V. Indication for Use

The Infrared Non-Contact Thermometers, ACT8100, is non-sterile, reusable clinical thermometers intended for the intermittent determination of human body temperature measured at the center of the forehead without contact. The device is intended for use on people of all ages, except pre-term babies or very small (small for gestational age). The device is intended for use in clinical and home use environments.

VI. Conformance Standards

The Infrared Non-Contact Thermometers conform to the following standards:

1. ISO 80601-2-56:2009 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
2. ASTM E1965-98:2009 Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature.
3. IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
4. IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
5. IEC 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
6. ISO 14971:2007 Medical Devices: Application of Risk Management to Medical Devices.
7. Software: FDA Guidance for the Content of Premarket Submissions for Software contained in Medical Device
8. ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
9. ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
10. ISO 10993-10: 2010 Biological evaluation of medical devices. Tests for irritation and delayed-type hypersensitivity

VII. Similarities/Differences between the subject and predicate device:

ELEMENT OF COMPARISON	Subject Device(s)	Predicate Device	Comparison
	ACT8100	No touch + forehead thermometer (NTF3000US)	
Classification	Thermometer Clinical Electronic, Class II Device	Thermometer Clinical Electronic, Class II Device	The device classifications are identical
Intended Use	A non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature measured at the center of the forehead without contact. The device is intended for use on people of all ages, except pre-term babies or very small (small for gestational age). The device is intended for use in clinical and home	A non-sterile, reusable clinical thermometer intended for the intermittent determination of the human's body temperature in a touch and no touch on the center of the forehead as the measurement site on people of all ages.	The intended use statements are similar
Sensor	**Infrared:** converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature when placed up to 2-8cm away.	**Infrared:** converts a user's forehead temperature using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature when placed in contact with the subject's forehead or up to 2 inches away.	Technological characteristics are similar

ELEMENT OF COMPARISON	Subject Device(s)	Predicate Device	Comparison
	ACT8100	No touch + forehead thermometer (NTF3000US)	
Power Requirement	ACT8100: 1.5V AAA size Alkaline battery *2	1.5V AA size battery *2	Battery size different, but the power requirements are similar (voltage outputs are the same)
Functionality	Dimensions: 163×44×26 mm	Dimensions: Length:148 Head: 44×26 mm Body: 37×24 mm	Head dimension is similar, the body length is different.
	Materials: All skin contacting materials have been tested in accordance with ISO 10993-1、-5、-10.	Materials: All skin contacting materials have been tested in accordance with ISO 10993-1、-5、-10.	Material characteristics all meet biological requirements
	Measuring ranges: 32.0ºC ~ 43.9ºC	Measuring ranges: 34.4ºC ~ 42.2ºC	All meet ASTM E 1965-98:2009
	Accuracy: 35.0 °C ~ 42.0 °C: ± 0.2 °C <35.0 °C or >42.0 °C: ± 0.3 °C	Accuracy: 35.0 °C ~ 42.0 °C: ± 0.2 °C Out of above range: ± 0.3 °C	All meet ASTM E 1965-98:2009
	Forehead measuring distance: 2~8 cm	Forehead measuring distance: 0~5 cm	Similar

VIII. Comparison of Technological Characteristics with the Predicate Device:

The technological characteristics of ACT8100 and predicate device (NTF3000US) are similar. Both convert user's forehead temperature using the infrared energy emitted in the area around the user's forehead to an oral equivalent temperature.

The differences between ACT 8100 and predicate device (NTF3000US) do not raise different questions of safety or effectiveness.

Difference	Difference Description	Reasons why not raising new questions
Battery size	ACT 8100 using AAA size, the predicated device (NTF3000US) using AA size	The output voltage is the same, and the differences are verified not to raise new questions regarding safety and effectiveness requirements within standard IEC60601-1 electrical safety requirements and IEC 60601-1-2 EMC test.
Dimensions	The design of shape is not very similar.	The differences are verified not to raise new questions regarding safety and effectiveness requirements within standard IEC60601-1 electrical safety requirements & ASTM E 1965-98:2009
Ambient measuring ranges	ACT 8100 (32.0ºC ~ 43.9ºC) is a little wider than The No Touch + Forehead Thermometer (34.4ºC ~ 42.2ºC).	The differences are verified not to raise new questions regarding safety and effectiveness requirements within standard IEC60601-1 electrical safety requirements & ASTM E 1965-98:2009
Forehead measuring distance(sensor)	The predicated device (NTF3000US) designed for both contact and no-contact. ACT 8100 is designed for only non-contact.	The differences are verified not to raise new questions regarding safety and effectiveness requirements within standard IEC60601-1 electrical safety requirements & ASTM E 1965-98:2009

IX. Non-Clinical Safety and Performance Testing

Non-clinical performance tests used to demonstrate the substantial equivalence of ACT 8100 to the predicate device. The device conforms to the requirements of laboratory accuracy, general electrical safety, electromagnetic compatibility and biocompatibility. Thus, the device has the same performance characteristics as the predicate device.

Non-Clinical Performance Testing	Standard/Guidance Applied and Conformed
Laboratory accuracy	ASTM E1965-98:2009 ISO 80601-2-56:2009
General Electrical Safety	IEC 60601-1:2012 IEC 60601-1-11:2010
Electromagnetic Compatibility	IEC 60601-1-2:2014
Biocompatibility	ISO 10993-1;ISO 10993-5; ISO 10993-10
Software	IEC 62304
Usability	IEC 62366
Risk Management	ISO 14971

X. Clinical Testing

A clinical study was performed to determine the clinical accuracy and to provide comparison with the predicate device. The three groups of subjects being tested were:
(1) Infants of under 1 year old, (2) Children between 1 to 5 years old, (3) Adults

Each group of subjects underwent a series of temperature measurement at their forehead and back of ear using ACT 8100 and BRUAN Infrared no touch + forehead thermometer NTF 3000. This series of measurement was intended to indicate and ultimately compare the repeatability of ACT 8100 and NTF 3000. The repeatability of both devices is found to be under 0.3℃, which is within the acceptable range as required by EN12470-5:2003, subclause 6.3.4. In addition, the repeatability of the both devices were found to be similar, further indicating that the ACT 8100 has reasonable accuracy and reliability. The three subject groups underwent a series of temperature measurement using the reference thermometer, Actherm Digital Clinical Thermometer ACT 2130 (K031905), either at the rectal, oral, or axillary site depending on their age group. These temperature measurements were then each compared to the temperature measurements taken by ACT 8100 and that of NTF 3000. The clinical biases of these measurements taken by ACT 8100 were found to be similar to that of NTF 3000, indicating that ACT 8100 produces effective and accurate temperature measurements.

XI. Conclusion

Infrared Non-Contact Thermometers, ACT8100 has similar intended use, principles of operation, and similar technological characteristics as the predicate device identified. Performance testing contained in this submission demonstrates the minor differences in technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. Results from the clinical study demonstrate substantial equivalence of accuracy and reliability of ACT 8100 and its similarity with NTF 3000. Thus, the Infrared Non-Contact Thermometer is substantially equivalent to the predicate device.