January 10, 2019

BroadMaster Biotech, Corp.
% Dr. Ke-Min Jen
Chinese-European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Taiwan 30067
China

Re: K180355
Trade/Device Name: Advocate Non-Contact Infrared Thermometer, Model: EF001A
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 30, 2018
Received: December 12, 2018

Dear Dr. Ke-Min 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180355

Device Name
Advocate Non-Contact Infrared Thermometer, EF001A

Indications for Use *(Describe)*
Advocate Non-Contact Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.

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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BroadMaster Biotech, Corp.
1F., 2F., No. 91, Xiyuan Rd., Zhongli Dist.,
Taoyuan City 32057, Taiwan (R.O.C.)
Tel: +886-3-451-7600
Fax: +886-3-451-9500
Website: www.broadmaster-biotech.com

I. 510(k) Summary *(Per 21 CFR 807.92)* K180355

Trade or proprietary name	*Advocate Non-Contact Infrared Thermometer, EF001A*
Common Name	Digital Thermometer
Classification Name	Clinical Electronic Thermometer 21 CFR 880.2910
Class	II
Panel	80 General Hospital
Product Code	FLL
Owner/Operator	**BroadMaster Biotech, Corp.** 1F., 2F., No. 91, Xiyuan Rd., Zhongli Dist., Taoyuan City 32057, Taiwan (R.O.C.) Tel: +886-3-451-7600 Fax: +886-3-451-9500 Website: www.broadmaster-biotech.com
Date prepared	December 28, 2018
510(k) Contact Person	Dr. Jen, Ke-Min Tel: +886-3-5208829 Fax: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
U.S. agent	Shu-Chen Cheng ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY 2064 Tamarin Dr. Columbus, OH, 43235 Phone: (614) 588-8168 Email: ceirs.jen@msa.hinet.net
Predicate Device	
Manufacturer:	Intrinity Global Limited
Product name:	Non Contact Infrared Forehead Thermometer
Model No:	TVT-200, TVT-200 PLUS
510(k) number:	K170662

- **Indications for Use:**
  Advocate Non-Contact Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people by detecting infrared heat from the forehead.

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- **Descriptions**

  The Advocate Non-Contact Infrared Thermometer model EF001A measures temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. The device is composed of a Probe of metals with infrared sensor inside to detect the infrared energy, an LCD Display, a SCAN button to start measuring temperatures, a Power switch button to switch on or off the device, a Body/Ambient button to switch between two measuring modes, and an Enclosure of ABS.

  The device has the following features: one-second measuring time, measuring Body or Ambient temperature, 12-memory recalls, $^{o}F/^{o}C$ unit switchable, over range message (Hi/Lo), low battery indication, auto display for the last reading when power is on, and auto shut-off when the device is idle for 60 seconds.

- **Principle Operation**

  The Advocate Non-Contact Infrared Thermometer measures temperatures of people by detecting the infrared energy radiated directly from the forehead without physical contact. As soon as the distance between the probe and the forehead is within 2 to 3.94 inches, the IR radiation sensor is activated, and the measurement will be taken instantly by detection of the infrared heat.

- **Predicate Device Comparison Table**

Comparison Items	**Predicate Device Non Contact Infrared Forehead Thermometer Model TVT-200, TVT-200 PLUS**	***Subject Device Advocate Non-Contact Infrared Thermometer Model EF001A***	***Remarks***
Indications for use	Non Contact Infrared Forehead Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of	*Advocate Non-Contact Infrared Thermometer is a non-sterile, reusable, handheld device. It can be used by consumers in homecare environment and doctors in clinic as reference. It is intended for measuring human body temperature of all ranges of people*	***Same***

BroadMaster Biotech, Corp.
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	people by detecting infrared heat from the forehead.	*by detecting infrared heat from the forehead.*	
Intended users	Lay user and professional	*Lay user and professional*	***Same***
Measurement method	Infrared radiation detection	*Infrared radiation detection*	***Same***
Measurement mode	Forehead measurement mode	*Forehead measurement mode*	***Same***
Measuring range	Body measurement mode: 89.6°F to 109.4°F (32°C to 43°C)	*Body measurement mode:* *89.6°F-109.4°F (32 °C - 43 °C)*	***Same***
Display resolution	0.1°F/ 0.1°C	*0.1 °F / 0.1 °C*	***Same***
°C/°F unit switchable	Yes	*Yes*	***Same***
Measuring accuracy	Body measurement mode: ±0.4°F/0.2°C (89.6°F to 109.4°F, 32°C to 43°C)	*Body measurement mode:* *±0.5 °F / 0.3°C* *(93.2°F -94.8°F, 34.0 °C-34.8°C)* *±0.4°F/0.2°C* *(95.0°F -107.6°F, 35.0 °C-42.0 °C)* *±0.5 °F/0.3 °C* *(107.8°F-109.4°F, 42.1°C-43.0°C)*	***Similar***
Display	LCD display	*LCD display*	***Same***
Measurement distance	0.39 inch (1 cm)	*2 - 3.94 inch (5-10 cm)*	***Different***
Memory set	16 sets	*12 sets*	***Similar***
Power source	One 1.5V AAA alkaline battery	*Two 1.5V AAA alkaline batteries*	***Similar***
Low battery indication	Yes	*Yes*	***Same***
Degree of protection	IP22	*IP20*	***Different***
Patient contact materials (colour coding)	Enclosure of pink, grey, orange and purple ABS, LCD Lens of PMMA and Probe of Metals	*Enclosure of red & black ABS,* *LCD Lens of PMMA and* *Probe of Metals*	***Same***
Principle operation information Operating condition	Detection of infrared heat energy from forehead 59°F~ 104°F (15°C~ 40°C) ≤95% RH	*Detection of infrared heat energy from forehead* *50.0°F- 104.0°F (10.0°F-40.0°C)* *≦ 80% RH*	***Same*** ***Similar***
Storage condition Cleaning method	Not available The thermometer enclosure and the measuring probe are cleaned and disinfected by 70% alcohol.	*-13.0°F-131°F (-25.0°F-55.0°C)* *≦ 95% RH* *The thermometer enclosure and probe can be cleaned and disinfected by 70% alcohol.*	***Similar*** ***Same***
Biocompatibility	Comply with ISO 10993-5:2009 & ISO 10993-10:2010	*Comply with* *ISO 10993-5:2009 &* *ISO 10993-10:2010*	***Same***
Electrical Safety	IEC 60601-1: 2005+CORR.1 (2006)+ CORR.2 (2007),	*IEC 60601-1: 2005/A1:2012*	***Same***
EMC	IEC 60601-1-2: 2014,	*IEC 60601-1-2:2014* *FCC 47 CFR Part 18, Subpart B*	***Same***
Performance	ASTM E1965-98 (2016), ISO 80601-2-56: 2009.	*ASTM E1965-98(2016)* *ISO 80601-2-56: 2017*	***Same***

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- **Comparison discussion:**

The main differences between two devices are the *measuring accuracy, measurement distance, memory set, power source, degree of ingress protection, operating conditions, and storage conditions.* We discuss those differences as below,

- The **measuring accuracy**, ±0.4°F/0.2°C, in the range of 95.0°F - 107.6°F (35°C - 42°C) are the same for two devices. The range of 95.0°F - 107.6°F (35°C- 42°C) is the most possibly used range for the regular practice. The accuracy, ±0.5°F/0.3°C, in the ranges of 93.2°F - 94.8°F and 107.8°F - 109.4°F are different from those of the predicate device, but the accuracy ±0.5°F /0.3°C still complies with the requirements of section 5.4.1, ASTM E1965-98 (2016). This difference does not raise any different questions of safety or effectiveness for the subject device.

- The **measurement distances** between the probe and the forehead are different for the predicate and subject devices. They are 0.39 inch for the predicate device and 2 - 3.94 inch for the subject device. The subject device's measurement distance is larger than the predicate device. It means the subject device can detect and receive the IR heat energy at a larger distance. As the measurement distance for the subject device is a range and is larger than the fixed value of the predicate device, the performance test complies with standard ASTM E1965-98. There are no safety and effectiveness concerns raised for the subject device due to the different measurement distance.

- The **memory sets** of the predicate device have 16 sets of temperature data and the subject device has12 sets of temperature data.. Since the memory sets are used for storing and recalling the temperature data taken previously by the users for reference, the different quantities of temperature data do not play a significant role in the usage for two devices. There are no safety and effectiveness concerns raised for the subject device due to this difference.

- The difference of the **power source** is the quantity of the 1.5V AAA alkaline batteries used, and the difference results from the different electric circuit voltages requirements, i.e. 1.5V for predicate device and 3.0V for subject device. This difference is related with the electric circuit component designs, and there are no safety and effectiveness concerns raised.

- The **ingress protection degrees** for predicate device and subject devices are IP22 and IP20 respectively. The dust ingress protections for two devices are the same and the liquid ingress protections are different. The subject device passed the cleaning test in the ASTM E 1965-98(2016) section 5.6.5, so the different liquid ingress protection levels between both devices will not raise any safety and effectiveness concerns for the subject device.

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- The **operating conditions** of two devices are different. The operating condition of the subject device is tested and validated to meet the requirements of ASTM E 1965-98 (2016), sections 5.6.1 & 5.6.2. Thus, the difference of operating conditions will not raise any safety and effectiveness concerns for the subject device.

- The **storage conditions** of the two devices are different. The storage condition of the subject device is tested and validated to meet the requirements of ASTM E 1965-98 (2016), section 5.6.4. Thus, the difference of the storage conditions will not raise any safety and effectiveness concerns for the subject device.

- **Non-Clinical Testing:**

Testing name	Referenced standard	Summary result	Verdict
Electric safety testing	IEC 60601-1:2005/A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	The subject device complies with the applicable requirements set forth in the referenced electric safety standard, IEC 60601-1:2005.	Pass
EMC testing	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	The subject device complies with the applicable requirements set forth in the referenced EMC standard, IEC 60601-1-2:2014.	Pass
EMC testing	FCC 47 CFR Part 18: Industrial, Scientific, And Medical Equipment, Subpart B: Applications and Authorizations	The subject device complies with the applicable requirements set forth in the referenced EMC standard, FCC 47 CFR Part 18.	Pass

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Performance testing	ASTM E1965-98(2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	The subject device complies with the applicable requirements set forth in the referenced performance standard, ASTM E1965-98(2016).	Pass
Performance testing	ISO 80601-2-56: 2017. Medical electrical equipment -- Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	The subject device complies with the applicable requirements set forth in the referenced performance standard, ISO 80601-2-56:2017.	Pass
Biocompatibility testing	ISO 10993-5:2009 *in vitro* Cytotoxicity test	The subject device complies with the applicable requirements set forth in the referenced biocompatibility standard, ISO 10993-5:2009.	Pass
Biocompatibility testing	ISO 10993-10:2010 Skin Irritation test	The subject device complies with the applicable requirements set forth in the referenced biocompatibility standard, ISO 10993-10:2010.	Pass
Biocompatibility testing	ISO 10993-10:2010 Sensitization test	The subject device complies with the applicable requirements set forth in the referenced biocompatibility standard, ISO 10993-10:2010.	Pass
Software validation and verification test	Guidance for the Content of Premarket Submissions for Software Contained in Medical	The software contained in the subject device complies with the	Pass

	Devices, issued on May 11, 2005	applicable requirements set forth in the referenced guidance document, "Guidance for the Content of Premarket Submissions for Software Contained, issued on May 11, 2005.	

- **Clinical Testing**

Name of clinical testing	**Summary of testing**	**Referenced standard**	**Patient population (age groups, number of subjects)**	**Result & Verdict**
Clinical test	The methods and criteria of EF001A Clinical Test had been assessed to meet the requirements of clinical accuracy per the referenced standards.	*ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometer For Intermittent Determination of Patient temperature	40 subjects in each age group, infants (0-1 year), children (1-5 years) and adults (>5 years) (Total 120 subjects)	Pass

- **Conclusion**

Performance tests were conducted on the subject device and all tests met specified criteria. Based on the information provided in this submission the subject device, Advocate Non-Contact Infrared Thermometer, model EF001A, is substantially equivalent to the predicate device.