September 5, 2019

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

Re: K191004
Trade/Device Name: Advocate Non-Contact Infrared Thermometer, Model EF001S
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: July 19, 2019
Received: August 6, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191004

Device Name
Advocate Non-Contact Infrared Thermometer, EF001S

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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510(k) Summary (Per 21 CFR 807.92)

510(k) number: K191004

Trade or proprietary name	Advocate Non-Contact Infrared Thermometer, model EF001S
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	July 19, 2019
Application Correspondent	Dr. Jen, Ke-Min ROC Chinese-European Industrial Research Society No. 58, Fu-Chiun St., Hsin-Chu City, 30067, Taiwan Tel: +886-3-5208829 Fax: +886-3-5209783 Email: ceirs.jen@msa.hinet.net
Predicate Device	
Manufacturer:	BroadMaster Biotech, Corp.
Product name:	Advocate Non-Contact Infrared Thermometer
Model No:	EF001A
510(k) number:	K180355

- **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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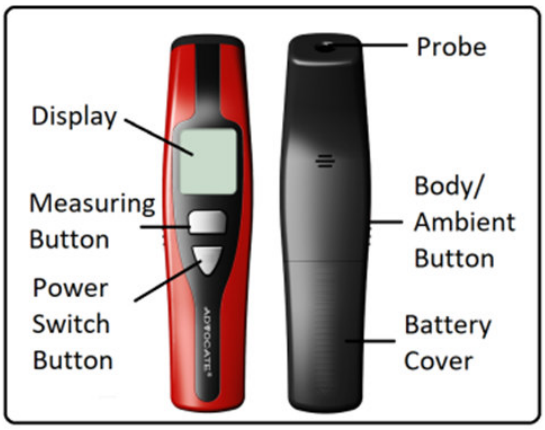
- **Descriptions:**

The Advocate Non-Contact Infrared Thermometer, model EF001S, 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, , as shown in the following diagram.

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, auto shut-off when the device is idle for 60 seconds and voice function. When the device starts, “Please measure” in English or “Mira la temperature” in Spanish will be heard. When completes, the result will be heard in additional to the data display. The Advocate Non-Contact Infrared Thermometer, model EF001S, including the voice function, is not intended for use by the visually impaired individuals.



Components of EF001S

- **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 -3.94 inches(5-10 cm), the IR radiation sensor is activated, and the measurement will be taken instantly by detection of the infrared heat.

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- **Substantial Equivalence Comparison Table**

Comparison Items	Predicate Device	*Subject Device*	*Remarks*
Applicant	*BroadMaster Biotech, Corp.*	*BroadMaster Biotech, Corp.*	***Same***
Proprietary (Trade) Name	*Advocate Non-Contact Infrared Thermometer*	*Advocate Non-Contact Infrared Thermometer*	***Same***
Model	EF001A	*EF001S*	***Series model***
510(k) No.	K180355	*K191004*	--
Classification Name and Regulation Number	thermometer, electronic, clinical 21 CFR 880.2910	*thermometer, electronic, clinical* *21 CFR 880.2910*	***Same***
Product Code	FLL	*FLL*	***Same***
Device Class	II	*II*	***Same***
Intended uses	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.	*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.*	***Same***
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℉ to 109.4℉(32 °C - 43 °C)	*Body measurement mode:* *89.6 ℉-109.4 ℉ (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:* *±0.5 °F / 0.3 °C* *(93.2 ℉ -94.8 ℉, 34.0 °C-34.8°C)* *±0.4 ℉/0.2°C* *(95.0 ℉ -107.6 ℉, 35.0°C-42.0 °C)* *±0.5°F/0.3 °C* *(107.8 ℉-109.4 ℉, 42.1°C-43.0 °C)*	*Body measurement mode:* *±0.5 °F / 0.3 °C* *(93.2 ℉ -94.8 ℉, 34.0 °C-34.8°C)* *±0.4 ℉/0.2°C* *(95.0 ℉ -107.6 ℉, 35.0°C-42.0 °C)* *±0.5°F/0.3 °C* *(107.8 ℉-109.4 ℉, 42.1°C-43.0 °C)*	***Same***
Display	LCD display	*LCD display*	***Same***
Measurement distance	*2-3.94 inch (5-10 cm)*	*2-3.94 inch (5-10 cm)*	***Same***
Memory set	12 sets	*12 sets*	***Same***
Power source	Two 1.5V AAA alkaline batteries	*Two 1.5V AAA alkaline batteries*	***Same***
Low battery indication	Yes	*Yes*	***Same***

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Degree of protection	IP20	*IP20*	***Same***
Operating condition	*50.0℉- 104.0℉ (10.0℃-40.0°C)* *≦ 80% RH*	*50.0℉- 104.0℉ (10.0℃-40.0°C)* *≦ 80% RH*	***Same***
Storage condition	*-13.0℉-131℉ (-25.0℃-55.0°C)* *≦ 95% RH*	*-13.0℉-131℉ (-25.0℃-55.0°C)* *≦ 95% RH*	***Same***
Cleaning method	The thermometer enclosure and probe can be cleaned and disinfected by 70% alcohol.	*The thermometer enclosure and probe can be cleaned and disinfected by 70% alcohol.*	***Same***
Human -contacting materials	*Enclosure of red & black ABS, LCD Lens of PMMA and Probe of Metals*	*Enclosure of red &black ABS, LCD Lens of PMMA and Probe of Metals*	***Same***
Biocompatibility	*EN ISO 10993-5:2009 &* *ISO 10993-10:2010*	*Complying EN ISO 10993-1:2009*	***Same***
Software	*Software validation report*	*Revised software validation report*	***Different***
Voice function	*No*	*Yes, extra 5 voice hardware: U3, U3A, C10 (10 uF), C13(0.1 uF) and Speaker*	***Different***
EMC	*IEC 60601-1-2:2014* *FCC 47 CFR Part 18, Subpart B*	*IEC 60601-1-2:2014* *FCC 47 CFR Part 18, Subpart B*	***Same***
Electrical Safety	*IEC 60601-1: 2005/A1:2012*	*ANSI AAMI ES60601-1:2005* *IEC 60601-1: 2005/A1:2012*	***Same***
Performance	*ASTM E1965-98(2016)* *ISO 80601-2-56:2017*	**Declaration of conformity to ASTM E1965-98(2016)* **Declaration of conformity to ISO 80601-2-56:2017*	***Same***
PCB	FR4 PCB	*FR4 PCB*	***Same***
Materials	Patient contacting materials is ABS (device housing / handle and button).	*Patient contacting materials is ABS (device housing / handle and button).*	***Same***
MCU	HYCON HY11P13 8-Bit RISC-like Mixed Signal Microcontroller Embedded 4x20 LCD Driver Low Noise Amplifier 18-Bit ADC	*HYCON HY11P13* *8-Bit RISC-like Mixed Signal Microcontroller* *Embedded 4x20 LCD Driver* *Low Noise Amplifier* *18-Bit ADC*	***Same***
Sensor	GE THERMOPILE IR SENSOR ZTP-148SR	*GE THERMOPILE IR SENSOR ZTP-148SR*	***Same***
LCD	TN LCD	*TN LCD*	***Same***
Speaker	Buzzer	*Speaker*	***Different***

- **Comparison discussion**

  Because the subject device is almost identical to the predicate device, except for the voice function, we will discuss the differences raised by the existence of voice function for the subject device.

  The software is different due to the addition of the voice function. However, software validation was performed and this difference of software did not raise any new or different questions of safety and effectiveness for the subject device.

  The extra 5 hardware components used by EF001S due to addition of the voice function are voice ICs:U3, U3A, C10 (10 uF), C13 (0.1 uF) and Speaker. Thus, we subjected the subject

device EF001S to meeting the provisions of Safety and EMC standards, i.e., ANSI AAMIES60601-1:2005, IEC 60601-1-2:2014, and FCC 47 CFR Part 18, Subpart B. This voice function is not intended for use by vision-impaired patients, and it is an auxiliary function for the lay users and medical professionals. So the voice function brings some convenience to the lay users and professionals. Regarding the extra 5 hardware components used by the subject device, there is no different or new safety and effectiveness questions.

- **Non-Clinical Testing**

Testing name	Referenced standard	Summary result	Verdict
Electric safety testing	ANSI AAMIES60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance FDA recognition number: 19-4	The subject device complies with the applicable requirements set forth in the referenced electric safety standard, ANSI AAMIES60601-1:2005.	Pass
EMC testing	IEC60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances- Requirements and tests, FDA recognition number: **19-8**	The subject device complies with the applicable requirements set forth in the referenced EMC standard, IEC 60601-1-2:2014.	Pass
	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
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 FDA recognition number: **6-403**	The subject device complies with the applicable requirements set forth in the referenced performance standard, ISO 80601-2-56:2017.	Pass
Biocompatibility testing	EN ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process FDA recognition number: **2-258**	The subject device EF001S has the same human-contacting materials as predicate device EF001A. There is no need to proceed the biocompatibility evaluation according to EN ISO 10993-1:2018.	Pass

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Revised Software Validation Report	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11,2005	The software contained inthe subject devicecomplies with the applicable requirements setforth in the referenced guidance document,"Guidance for the Contentof Premarket Submissions forSoftware Contained, issue done May 11, 2005.	Pass

- **Clinical Testing**

Name of clinical testing	**Referenced standard**	**Summary of testing**	**Patient population (age groups, number of subjects)**	**Verdict**
EF001Clinical Accuracy	*ASTM E1965-98(2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature FDA recognition number: **6-125**	The methods and criteria of EF001 Clinical Test had been clinically assessed to meet the requirements of clinical accuracy per the referenced standards.	40 subjects in each age group, infants (0-1 year), children (1-5 years) and adults (>5 years) (Total 120 subjects)	Pass

- **Conclusion**

Non-clinical performance and clinical 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, EF001S, is substantially equivalent to the predicate device, EF001A.