March 27, 2019

Tyto Care Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K190242
Trade/Device Name: Tyto Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical electronic thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 8, 2019
Received: March 11, 2019

Dear Dave Yungvirt:

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,

Geeta K.
Pamidimukkala -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)*
K190242

Device Name
Tyto Thermometer

Indications for Use *(Describe)*
The Tyto Thermometer is a non - contact clinical infrared thermometer intended for intermittent determination of human body temperature from the center of the forehead on people of all ages. The Tyto Thermometer is intended for use by both adult lay users and clinicians. It can be used both at home and in clinic 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.

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

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510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name and Address:	Tyto Care Ltd. 12 Haomanut Street Netanya, Israel, 4250445
Contact Person:	Stella Raizelman Perry RA Director Email: stellar@tytocare.com Phone Number: +972 72-2210750 Fax Number: +972 72-2210752
Establishment Registration Number:	3012678246
510(k)	K190242
Date Prepared:	March 15, 2019
Device Trade Name(s):	Tyto Thermometer
Device Common Name:	Forehead Thermometer
Classification:	**Name:** Clinical electronic thermometer **Product code:** FLL **Regulation No:** 21 CFR 880.2910 **Class:** II **Panel:** General Hospital
Predicate Device(s):	

Device name	**510(k) No.**	**Date of Clearance**
No Touch + Forehead Thermometer NFT3000	K134043	May 21, 2014

The CliniCloud Thermometer (K161325) is used as the Reference Device. The CliniCloud Thermometer provides an example of a cleared device that communicates wirelessly to a smart phone application.

Intended use / indication for use statement

The Tyto Thermometer is a non- contact clinical infrared thermometer intended for intermittent determination of human body temperature from the center of the forehead on people of all ages. The Tyto Thermometer is intended for use by both adult lay users and clinicians. It can be used both at home and in clinic environments.

Device description

The Tyto Thermometer is a non-contact infrared thermometer that enables measuring of the human body temperature for persons of all ages. The device is a hand-held infrared thermometer that, when positioned within 2 inches of a patient's forehead, measures the infrared energy emitted from the surface of the skin and converts it to a Core body temperature scale (Celsius, Fahrenheit) as represented on the oral body site. The device is designed for use by professional as well as lay users in clinical or non-clinical environments. The device can optionally be connected wirelessly to a user's mobile phone for use with a dedicated app (TytoCare App). Measurement results are displayed on the device LCD screen and in parallel on the mobile phone. Results of temperature recordings can be stored on the Tyto Server.

Substantial Equivalence to Predicate Devices

The following table compares the Tyto Thermometer to the predicate device:

	Proposed Device	**Predicate**
Device Name	Tyto Thermometer	No Touch + Forehead Thermometer (Model NTF3000US)
Device Class	Class II	Class II
Classification Panel	General Hospital and Personal use Monitoring Devices	General Hospital and Personal use Monitoring Devices
Product code	FLL	FLL
Regulation number	21 CFR 880.2910 Clinical electronic thermometer	21 CFR 880.2910 Clinical electronic thermometer
Regulation description	Clinical electronic thermometer	Clinical electronic thermometer
Intended use and indication for use	The Tyto Thermometer is a clinical infrared	The No Touch + Forehead Thermometer (Model

	Proposed Device	Predicate
	thermometer intended for intermittent determination of human body temperature on the center of the forehead as the measurement site on people of all ages. The Tyto Thermometer is intended for use by both adult lay users and clinicians. It can be used both at home and in clinic environments.	NTF3000US) is a non-sterile, reusable clinical thermometer intended for the intermittent determination of human body temperature in a touch and no touch on the center of the forehead as the measurement site on people of all ages.
Technological Characteristics	Infrared sensor	Infrared sensor
Measuring Method	Detection of infrared energy and use of predictive algorithms to estimate the body temperature	Detection of infrared energy and use of predictive algorithms to estimate the body temperature
Resolution	0.1°C / 0.1°F	0.1°C / 0.1°F
Laboratory Accuracy	±0.2°C (0.4°F) on 36°C - 39°C (96.8°F - 102.2°F) range, ±0.3°C (0.5°F) accuracy outside the above range.	± 0.2°C on 35.5°C – 42.0°C range (± 0.4°F on 95.9°F – 107.6°F range) ± 0.3°C (± 0.5°F) outside this range
Temperature Display	LCD Graphical display	Liquid Crystal Display, 4 digits plus special icons
Measurement Site	Forehead: center	Forehead: center
Operating Conditions of use (ambient temperature)	16°C - 40°C (60.8 - 104°F)	15 °C – 40 °C (59 °F – 104 °F)
Storage Conditions (temperature/ humidity/air pressure)	-20°C – 60 °C (-4 - 140°F)	–25 °C - 60 °C (-13°F - 140 °F)
Measuring Range	34.4°C – 42.2 °C (94.0 – 108.0 °F)	34.4 °C – 42.2 °C (94.0 -108 °F)
Power Requirements	Li-ion, built-in, rechargeable	2 AA Batteries

	Proposed Device	Predicate
Wireless Communication	wi-fi connection & data transfer to the mobile device running the TytoCare app.	None
Display	Liquid Crystal Display	Liquid Crystal Display
Battery Life	Up to 300 cycles of charge/discharge	Up to 1000 measurements
Power supply	Proprietary plug, 2A wall charger, US plug, Input: 100-240Vac ~50-60Hz, 500mA; Output: 5Vdc@2A	N/A
Size	85 x 73 x 47 mm (3.35 x 2.87 x 1.85 inch)	L = 148 mm (5.83 in.) x Diameter=50mm(1.97in)
Weight	0.33 lbs. (150g)	99.5 g (with batteries), 77.1 g (w/o batteries)
Biocompatibility	All parts that are in contact with the operator comply with the requirements of ISO 10993-1	All parts that are in contact with patient/operator comply with the requirements of ISO 10993-1
Software	was verified and validated according to the FDA guidance.	was verified and validated according to the FDA guidance.

All above devices are indicated for over the counter use. The Tyto Thermometer, like its predicate device the Kaz NTF3000 (K134043) are both intended for intermittent determination of human body temperature for people of all ages. Thus, the device meets the first requirement for a finding of substantial equivalence. The submission includes comparison of technological elements of the subject devices and predicate device in accordance with the Clinical Thermometer FDA guidance document, including comparison of labeling, components, materials, precision and repeatability and response time among others. The subject and predicate device have similar design features, both are handheld devices used for performing non-contact temperature recordings using infrared sensor to record a user's forehead temperature, which is converted to an oral equivalent temperature. The temperature measure for the subject device and the predicate thermometer is performed using a thermopile sensor with

integrated thermistor for the target reading. Both the Tyto Thermometer and the predicate also use a thermistor for ambient temperature readings. Temperature measurements are obtained within 3 seconds, comparable to the 2 second response time of the predicate device. The temperature reading is obtained very quickly with both the Tyto device and the Kaz predicate, and the additional 1 second to obtain the reading does not raise any questions of safety or effectiveness.

Materials used in the manufacture of the subject device are similar to the predicate device. All skin contacting materials used meet the requirements for biocompatibility in accordance with ISO 10993-1.

Any minor differences between the Tyto Thermometer and its predicate device do not raise different questions of safety and efficacy. Additionally, test methods equivalent to those used to evaluate the predicates exist to evaluate the device and the testing demonstrated comparable performance.

Performance testing - Bench:

A testing plan was developed and performed in order to verify that the Tyto Thermometer meets its specifications and demonstrates, based on comparable characteristics, similar performance and safety as compared to its predicate device. The main aspects of the testing plan included:

- Electrical safety and electromagnetic compatibility testing (according to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) +Am.1 (2012) , IEC 60601-1-11: 2015 and IEC 60601-1-2: 2014)
- Biocompatibility assessment according to ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", "ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity" and "ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization"

- Performance testing (According to ASTM E1965 – 98 (R 2009) Standard for Infrared Clinical Thermometers, wireless coexistence)
- The software was assessed according to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005". The overall level of concern was found to be moderate, with verification and validation testing confirming that the software performs as intended and is compliant to requirement and specification documents
- Cybersecurity Threat Analysis to assess the cybersecurity threats was performed according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued on October 2, 2014"

The results from this testing demonstrate that the Tyto Thermometer meets its specifications, and has substantially equivalent performance to its predicate.

Clinical Performance validation

The clinical validation study in accordance with ASTM E1965-98 (R 2009) and ISO 80601-2-56 (2009) was conducted to compare the Tyto Thermometer and the predicate device. The validation study included data from 124 subjects. The subjects were divided into 3 study groups by age: Group 1: up to 1 year (Sub-group 1a up to 3 months and Sub-group 1b 3 months up to 1 year), Group 2: 1 to 5 years and Group 3: older than 5 years. Within each age group both afebrile and febrile subjects were represented. The results from the clinical validation demonstrated that the Tyto Thermometer meets its specifications and has substantially equivalent performance to the predicate Thermometer in all age groups with respect to the bias and standard deviation in comparison to the reference gold standard Welch Allyn contact thermometers. The repeatability of the Tyto Thermometer was clinically and statistically acceptable for all age groups and Sub-groups. Hence, the Tyto Thermometer was able to meet the pre-defined criteria for accuracy and precision and the primary performance endpoint of the study has been met.

Conclusion

As outlined in this section, the Tyto Thermometer has similar intended use and fundamental technological characteristics as its predicate device, the KAZ NFT3000 (K134043). Any minor differences in intended use or technology between the Tyto Thermometer and its predicate do not raise different questions of safety or effectiveness. Furthermore, testing and clinical validation demonstrate that the performance of the Tyto Thermometer is comparable to its predicate device. Consequently, it is concluded that the Tyto Thermometer can be considered substantially equivalent to its predicate device.