



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

June 22, 2016

StethoCloud Pty. Ltd.
c/o Mr. Dave Yungvirt
Third Party Review Group, LLC.
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K161325

Trade/Device Name: CliniCloud Non-Contact Thermometer, Model SPL1024
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 30, 2016
Received: June 1, 2016

Dear Mr. 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. 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" (21CFR 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
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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

Indications for Use

510(k) Number (if known)

K161325

Device Name

CliniCloud Non-Contact Thermometer, Model SPL1024

Indications for Use (Describe)

The CliniCloud Non-Contact Thermometer is an infrared thermometer intended for the periodic measurement of human body temperature for persons of all ages, to be used in conjunction with the CliniCloud app.

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

CliniCloud Non-Contact Thermometer

K161325

1. Submission Sponsor

StethoCloud Pty. Ltd (CliniCloud)
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Australia
Contact: Andrew Lin
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2. Submission Correspondent

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3. Date Prepared

June 22, 2016

4. Device Identification

Trade/Proprietary Name:	CliniCloud Non-Contact Thermometer, Model SPL1024
Common/Usual Name:	Forehead Thermometer
Classification Name:	Clinical Electronic Thermometer
Regulation Number:	880.2910
Product Code:	FLL – clinical electronic thermometer
Device Class:	Class II
Review Panel:	General Hospital

Legally Marketed Predicate Device(s)

K131243, Non-contact Infrared Thermometer JPD-FR100, Shenzhen Jumper Medical Equipment Co., Ltd.

The Wireless Thermometer WT701 by Raiing Medical Company (K132761) is used as the Reference Device. The Raiing Medical Thermometer provides an example of a cleared device that communicates wirelessly to a smart phone application as the receiver.

5. Device Description

The CliniCloud Non-Contact Thermometer Model SPL1024 (abbreviated 'CliniCloud Non-Contact Thermometer') is a battery powered Bluetooth Low Energy (BLE) enabled portable infrared thermometer intended for the measurement of human body temperature for persons of all ages. It features no physical buttons or a display and must be used in conjunction with the CliniCloud App on a compatible BLE enabled smartphone. The CliniCloud App is free to download.

When power is applied to the device via 2 AAA batteries, the CliniCloud Non-Contact Thermometer starts to advertise via BLE, and can establish a BLE connection with BLE enabled smart phones with the CliniCloud app. The user could then request the CliniCloud non-contact thermometer to take temperature readings from within the CliniCloud app. The measured temperatures are sent back to the smart phone via the established Bluetooth link and displayed on the smartphone's display in the CliniCloud app. The CliniCloud Non-Contact Thermometer uses a medical grade MLX90614ESF-DCC thermopile sensor supplied by Melexis to passively measure object surface temperature using infrared radiation emitted by patients. The sensor also measures the ambient temperature with a built-in thermistor. The sensor is factory calibrated to meet consensus standard ASTM E1965-98. Upon receiving a request from the CliniCloud APP over the established BLE connection the onboard Nordic Semiconductor NRF51822 BLE SOC microcontroller communicates with the thermopile (MLX90614ESF-DCC) over the I2C bus and sends the received temperature readings including the object surface temperature and the ambient temperature to the CliniCloud app via the established BLE connection. On the smartphone app, the well-known heat loss equation is used to perform conversion of forehead surface temperature to oral equivalent temperature.

6. Indication for Use Statement

The CliniCloud Non-Contact Thermometer is an infrared thermometer intended for the periodic measurement of human body temperature for persons of all ages, to be used in conjunction with the CliniCloud app.

7. Substantial Equivalence Discussion

The following table compares the CliniCloud Non-Contact Thermometer to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. A reference device was used to support substantial equivalence since the subject device does not have the same technological characteristics (i.e. Bluetooth connectivity and display) as the predicate device. Aside from minor differences in the indications for use statements, i.e. the use environment is not included in the indications for use statement; the CliniCloud Non-Contact Thermometer has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device and conclude that these differences do not alter the intended use of the device.

Table 5A – Comparison of Characteristics

Manufacturer	StethoCloud Pty. Ltd (CliniCloud)	Shenzhen Jumper Medical Equipment Co., Ltd.
Trade Name	CliniCloud Non-Contact Thermometer, Model SPL1024	Non-contact Infrared Thermometer JPD-FR100
510(k) Number	K161325	K131243
Product Code	FLL – clinical electronic thermometer	FLL – clinical electronic thermometer
Regulation Number	880.2910	880.2910
Regulation Name	Clinical Electronic Thermometer	Clinical Electronic Thermometer
Indications for Use	The CliniCloud Non-Contact Thermometer is an infrared thermometer intended for the periodic measurement of human body temperature for persons of all ages, to be used in conjunction with the CliniCloud app.	The non-contact infrared thermometer, model JPD-FR100, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.
Measurement method	Infrared radiation detection	Infrared radiation detection
Measurement mode	Forehead measure mode	Forehead measure mode
Measuring Range	32.2°C – 43.3°C (90.0°F – 109.9°F)	32.2°C – 43.3°C (90.0°F – 109.9°F)
Display resolution	0.1°C (0.1°F)	0.1°C (0.1°F)
Measuring accuracy	± 0.2°C (0.4°F)	± 0.2°C (0.4°F)
Standards met	ASTM E1965-98	ASTM E1965-98
C/F switchable	Yes	Yes
Recommended measurement distance	0.1-5cm	1-6cm
Display	Smartphone device Display	LCD display
Working voltage	3V	3V
Memory	Readings are stored on smartphone via app and limited by smartphone hard-drive capacity	20 sets
Battery	2 x 1.5V AAA	2 x 1.5V AAA
Low battery indication	Yes	Yes

Manufacturer	StethoCloud Pty. Ltd (CliniCloud)	Shenzhen Jumper Medical Equipment Co., Ltd.
Trade Name	CliniCloud Non-Contact Thermometer, Model SPL1024	Non-contact Infrared Thermometer JPD-FR100
Waterproof	No	No
Dimension	115 x 36 x 25 mm	145 x 60 x 50 mm
Weight	80g	180g
Recommended operating condition	15°C to 40.0 (59°F to 104.0°F) ≤85%, non-condensing	10°C – 40.0°C (50°F – 104.0°F) <95% humidity, non-condensing
Signal transmission	Wireless 2.4G Bluetooth LE	None

As seen in the comparison table, the subject and predicate devices have similar design features and performance specifications. One of the main technological differences between the subject and predicate devices are related to the wireless transmission characteristics in which a reference device was used to support the Bluetooth connectivity. A reference device, K132761, Raiing Wireless Thermometer WT701 was used to demonstrate equivalence for the Bluetooth connectivity. Another technological difference is the display. The subject device uses a smartphone display via the CliniCloud App whereas the predicate device uses a built-in LCD display.

These differences, however, do not raise different questions of safety or effectiveness. As demonstrated in the non-clinical testing, the different technological characteristics do not affect the safety and effectiveness of the CliniCloud Non-Contact Thermometer.

8. Non-Clinical Performance Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- Requirements and tests
- FCC Part 15 Subpart C test FCC Part 15.247
- ASTM E1965-98: (R 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
- Biocompatibility testing standards for components that have limited skin contact for the user only, including, “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”

- ISO 14971:2007 Medical devices - Application of Risk Management to Medical Devices

The proposed device also passed performance testing, which included wireless coexistence testing, transmission distance testing, measuring distance testing, usability testing, device accuracy testing and comparison testing to the predicate device under use case environment. 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.

9. Clinical Performance Data

Validation study was performed to clinically validate the CliniCloud thermometer, Model SPL1024, per the specification of ASTM E1965-98, under three (3) different environment settings. This validation study includes data from 60 subjects, 1 subject device, 1 predicate device and 4 calibrated reference devices (same model) used as gold standard. Study included 85% males and 15% females. The validation study demonstrated that the clinical accuracy of the CliniCloud thermometer and the predicate devices yielded equivalent accuracy.

Both the clinical and non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics, but can be demonstrated that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The CliniCloud Non-Contact Thermometer, as designed and manufactured, is determined to be substantially equivalent to the predicate device.