K111308

510(k) Summary

AUG 30 2011

Contact Details

Applicant Name: ZYTO Technologies, Inc
387 S. 520 W., Ste. 200
Lindon, UT 84042

Phone: 801-224-7199
Fax: 801-221-4662

Contact Person: Vaughn R Cook, CEO
Email: DrCook@ZYTO.com

Date Prepared: July 13, 2011

Device Name

Trade Name: ZYTO Hand Cradle

Common Name: Galvanic Skin Response Measurement Device

Classification Name: GZO

Legally Marketed Predicate Device(s)

510(k) Number	Product Code	Trade Name	Applicant
K943101	GZO	GALVANIC SKIN RESPONSE DEVICE	GLOBAL ENT.

Device Description

The ZYTO Hand Cradle is a Galvanic Skin Response Measurement Device. The device is designed, owned, manufactured, and distributed by ZYTO Technologies, Inc. The device consists of electrical circuit boards encased in a plastic/metal case. The device is non-invasive and comes in contact with the patient via conductive contacts (the equivalent of a stylus and hand-mass) incorporated into one piece, using the same functionality as the predicate device. The device connects to a computer to supply data to an operator.

Intended Use/Indications for use

The measurement of Galvanic Skin Response; Prescription Use

Substantial Equivalence Comparison

The ZYTO Hand Cradle is substantially equivalent to the predicate device for the following reasons:

1. Intended Use
2. Technological Characteristics:
    a. Voltage used to collect the measurement (when duty cycle is considered).
    b. Measurement ranges and the responses within those ranges.
    c. Both designed for use at multiple sampling locations on the skin. (Predicate device requires operator moving stylus between sampling locations; ZYTO Hand Cradle samples five separate locations without operator manipulation.)
    d. Both interface to a computer for display of data.
3. Both are designed for use with intact skin.
4. Performance data is equivalent.

Non-clinical Testing

Bench tests were conducted using the predicate device and the ZYTO Hand Cradle to determine performance equivalency. Resistors of varying values were placed across the opposite polarities on each device and the resultant reading was noted. Data was then plotted graphically and the responses were substantially the same. These test results are included with this summary.

In December 2010 ZYTO retained SDP Engineering in Lake Forest, CA to conduct independent third party tests in accordance with EN60601-1-2 and EN55011 CLASS B PCC Part 15B. The complete report from SDP Engineering is included in the submission. The submission device (ZYTO Hand Cradle) met all testing requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ZYTO Technologies, Inc.
c/o Vaughn R. Cook, OMD
CEO
387 S. 520 W., Suite 200
Lindon, UT 84042

AUG 30 2011

Re: K111308
Trade/Device Name: ZYTO Hand Cradle
Regulation Number: 21 CFR 882.1540
Regulation Name: Galvanic Skin Response Measurement Device
Regulatory Class: Class II
Product Code: GZO
Dated: July 14, 2011
Received: July 15, 2011

Dear Dr. Cook:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AUG 3 0 2011

Indications for Use

510(k) Number (if known): K111308

Device Name: ZYTO Hand Cradle

Indications For Use: The measurement of Galvanic Skin Response

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K111308