K060820

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SunTech Medical®

SunTech Medical, Inc.
Abbreviated 510(k) Submission
Cycle BP Monitor and Pulse Oximeter
510(k) Summary
March 22, 2006

JUN - 7 2006

(1) Submitter information

Name:	SunTech Medical, Inc
Address:	507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200
Telephone:	919.654.2332
FAX:	919.654.2301
Contact person:	David Gallick (Official Correspondent).
	SunTech Medical 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2332 Fax: 919-654-2301
Date prepared:	March 22, 2006

(2) Name of Device

Trade Name:	Cycle BP Monitor and Pulse Oximeter
Common Name:	NIBP Monitor
Classification name:	Noninvasive blood pressure measurement system, 870.1130

(3) Legally-marketed predicate devices

Sun Tech Medical has identified its Tango+, K053209, as the predicate device for the Cycle BP Monitor and Pulse Oximeter.

The Cycle BP Monitor and Pulse Oximeter is substantially equivilent to this device.

(4) Description

The Cycle BP Monitor and Pulse Oximeter, a microprocessor based ambulatory blood pressure monitor and oxygen saturation measurement system compatible with ergometer stress-test systems, uses Korotkoff sounds to determine blood pressure and an optical finger sensor for oxygen saturation. An internal electric pump is used to inflate the cuff, and deflation is controlled by two valves. The Cycle has the ability to make blood pressure at predetermined intervals (normally from a schedule determined by the physician), or on demand. Saturation measurements are updated once per second.

(5) Intended Use

The SunTech Medical Cycle BP monitor and Pulse Oximeter is indicated for use in measuring and displaying Systolic and Diastolic blood pressures, heart rate, and functional saturation of arterial hemoglobin (SpO_2) of adult and pediatric patients in hospitals, medical facilities and subacute environments.

(6) Comparison to Predicate Devices

The Cycle BP Monitor and Pulse Oximeter has the same basic construction as the predicate device. Both devices are microprocessor controlled and the devices utilize similar circuitry. The Cycle is made from the same materials as the Tango+. It uses the same BP cuffs and SpO_2 sensors as the Tango+. The Cycle utilizes the same BP measurement range and the same SpO_2 range as the Tango+. The Cycle includes Pediatrics in the patient population. The Cycle BP monitor identifies the Korotkoff signals without the use of R-wave gating as used by the Tango+.

(7) Testing and Validations

The Cycle BP Monitor has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- AAMI SP10: 2002
- IEC 60601-1:1996
- IEC 60601-2-30:1999
- ISO 9919:1992
- IEC 60601-1-2:2001
- IEC 60601-1-4:2000
- IEC 60601-2-49:2001
- Functional Specification, (SunTech document # 99-0049-XX-FS)

(8) Conclusion

The Cycle BP Monitor and Pulse Oximeter is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2006

SunTech Medical, Inc.
c/o Mr. David Gallick
Vice President, Engineering
507 Airport Blvd., Suite 117
Morrisville, NC 27560-8200

Re: K060820
Trade Name: Cycle BP Monitor and Pulse Oximeter, Model 1060
Regulation Number: 21 CFR 870.1130, and 21 CFR 870.2700
Regulation Name: Noninvasive Blood Pressure Measurement System, and Oximeter
Regulatory Class: Class II (two)
Product Code: DXN and MUD
Dated: May 25, 2006
Received: May 26, 2006

Dear Mr. Gallick:

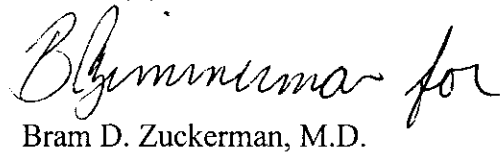
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known): K060820

Device Name: Cycle BP Monitor and Pulse Oximeter

Indications for Use:

The SunTech Medical Cycle BP monitor and Pulse Oximeter is indicated for use in measuring and displaying systolic and diastolic blood pressures, heart rate, and functional saturation of arterial hemoglobin (SpO_2) of adult and pediatric patients in hospitals, medical facilities and subacute environments.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060820