DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

JAN - 2 1998

Mr. David Gallick
Quality Assurance Manager
SunTech Medical Instruments, Inc.
8917 Glenwood Avenue
Raleigh, NC 27612

Re: K970629
Tango Non-Invasive Blood Pressure Monitor
Regulatory Class: II (Two)
Product Code: DXN
Dated: November 3, 1997
Received: November 4, 1997

Dear Mr. David Gallick:

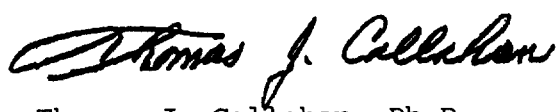
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970629

Device Name: Tango Non-invasive Blood Pressure Monitor

Indications For Use:

See Attached Sheet

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970629

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Indications for Use: **SunTech Medical Instruments**
Tango Non-invasive Stress BP Test Monitor JAN - 1 1998

The Tango Blood Pressure Monitor is intended for use as an aid or adjunct to ECG exercise stress testing, measuring and displaying an adult patients systolic and diastolic blood pressures.

The Tango Monitor has two operating modes, Dimensional K-Sound (DKA) and Oscillometry.

In the Oscillometric mode the Tango NIBP monitor measures:

1. Systolic Pressure (mmHg)
2. Diastolic Pressure (mmHg)
3. Pulse Rate (beats per minute)

In the Dimensional K-Sound mode (DKA) the Tango NIBP monitor measures:

1. Systolic Pressure (mmHg)
2. Diastolic Pressure (mmHg)
3. Heart Rate (beats per minute)

Depending on the mode the Monitor is in one of the following waveforms are displayed:

1. R-Wave trigger signal (DKA)
2. K-sound waveforms (DKA)
3. or Oscillometric pressure pulses (Oscillometric)

Intended Patient Population

The Tango NIBP monitor is only intended for use as a stress test monitor. The unit is not intended for use with children, neonates or geriatrics. The Tango monitor is limited to adult use, the age range for the unit is 18 and older. Arm sizes are limited to the following cuff sizes:

Small Adult	18cm - 26 cm
Adult	25 cm - 35 cm
Large Adult	33 cm - 47 cm

Intended Operators and Environment

The Tango NIBP monitor is intended to be operated by a nurse, physician or clinician for stress/exercise tests. The Tango is only intended to be used in a hospital, clinic and stress test lab. There are no circumstances were the Tango NIBP monitor would be operated by a patient or outside of hospital, clinic or stress test lab.

The Tango has been tested and meets the environmental operating conditions required by AAMI SP10. Refer to Appendix B1 for the AAMI SP10 test results.