K093501 p1/2

510(k) Summary

NOV 24 2009

Submission Date: 03 November 2009

Submitter:
Spacelabs Medical, Inc.
5150 220th Avenue SE
Issaquah, WA 98029 USA

Submitter Contact:
David J. Geraghty
Phone: +1 (425) 657-7200, ext 5889
Fax: +1 (425) 657-7210
Email: david.geraghty@spacelabs.com

Trade Name: *élance* Vital Signs Monitor and *élance* Central Station

Common Name: Patient Physiological Monitor (with arrhythmia detection or alarms)

Classification Name: Monitor, physiological, patient (with arrhythmia detection or alarms)

Classification Regulation: 21 CFR §870.1025

Product Code: MHX

Substantially Equivalent Devices:

New Spacelabs Model	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
élance Vital Signs Monitor and *élance* Central Station	K090556	Spacelabs Healthcare Medical Equipment (Suzhou) Co., Ltd. / *élance* Vital Signs Monitoring System; and, *élance* Central Monitor

Device Description: The Spacelabs Medical, Inc. (Spacelabs) *élance* Vital Signs Monitor is a family of portable patient monitors intended to be used by clinicians and medical qualified personnel for monitoring ECG, respiration, NIBP, temperature, SPO_2, invasive blood pressure and $EtCO_2$. Models within the Spacelabs *élance* family come in two different sized viewing areas (10.2" and 12.1"), two different housing colors (white and black) and offer selected monitoring features.

Central Station: The Spacelabs Medical, Inc. *élance* Central Station software package is available for use with a customer acquired computer based on specifications provided by Spacelabs Medical. This package allows monitoring of the *élance* Vital Signs Monitor at a central workstation.

Technology Comparison:	The *élance* Vital Signs Monitor and *élance* Central Station utilize the same technology for each parameter as utilized by the predicate device.
Intended Use:	The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is indicated for use in patient populations for: - Adult - Pediatric The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station facilitates the monitoring of: - ECG with arrhythmia detection - Respiration - Non-invasive blood pressures - Invasive blood pressures - Body temperature - Functional arterial oxygen saturation, and - End tidal CO_2. The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.
Performance Testing:	Device modifications made to the *élance* Vital Signs Monitor and *élance* Central Station were appropriately verified to ensure that each modification was implemented correctly. Verification results indicated that the *élance* Vital Signs Monitor and *élance* Central Station complies with predetermined specifications.
Conclusion	Based upon a comparison of devices and verification results, the Spacelabs *élance* Vital Signs Monitor and *élance* Central Station are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 2 4 2009

Mr. David J. Geraghty
Manager, Regulatory & Quality
Spacelabs Medical, Inc.
5150 220th Ave SE
P.O. Box 7018
Issaquah, WA 98027-7018

Re: K093501
Device Name: *élance* Vital Signs Monitor and *élance* Central Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (Two)
Product Code: MHX
Dated: November 3, 2009
Received: November 12, 2009

Dear Mr. Geraghty:

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.

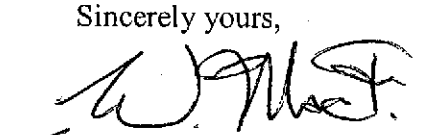
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for 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): K093501

Device Name: Spacelabs Medical, Inc. (Spacelabs) *élance* Vital Signs Monitor and *élance* Central Station

Indications for Use: The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is indicated for use in patient populations for:

- Adult
- Pediatric

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station facilitates the monitoring of:

- ECG with arrhythmia detection
- Respiration
- Non-invasive blood pressures
- Invasive blood pressures
- Body temperature
- Functional arterial oxygen saturation, and
- End tidal CO_2.

The Spacelabs *élance* Vital Signs Monitor and *élance* Central Station is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 Cardiovascular Devices

510(k) Number K093501