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NORTHROP GRUMMAN

Advanced Technology and
Development Center
Northrop Grumman Corporation
8900 East Washington Boulevard
Pico Rivera, California 90660-0158
Telephone 310 948-9161

**SECTION 16
FDA 510(k) SUMMARY**

Submitted By

Company: Northrop Grumman Corporation (NGC)
Advanced Technology and Development Center (ATDC)
N560/XA
8900 E. Washington Blvd.
Pico Rivera, CA 90660

Contact Person: Louis S. Toth
LSTAT Project Engineer
(310) 948-6482 (voice)
(310) 948-9485 (FAX)

Date: December 17, 1996

Name of the Device

Trade Name: Life Support for Trauma and Transport (LSTAT)
Model 9601

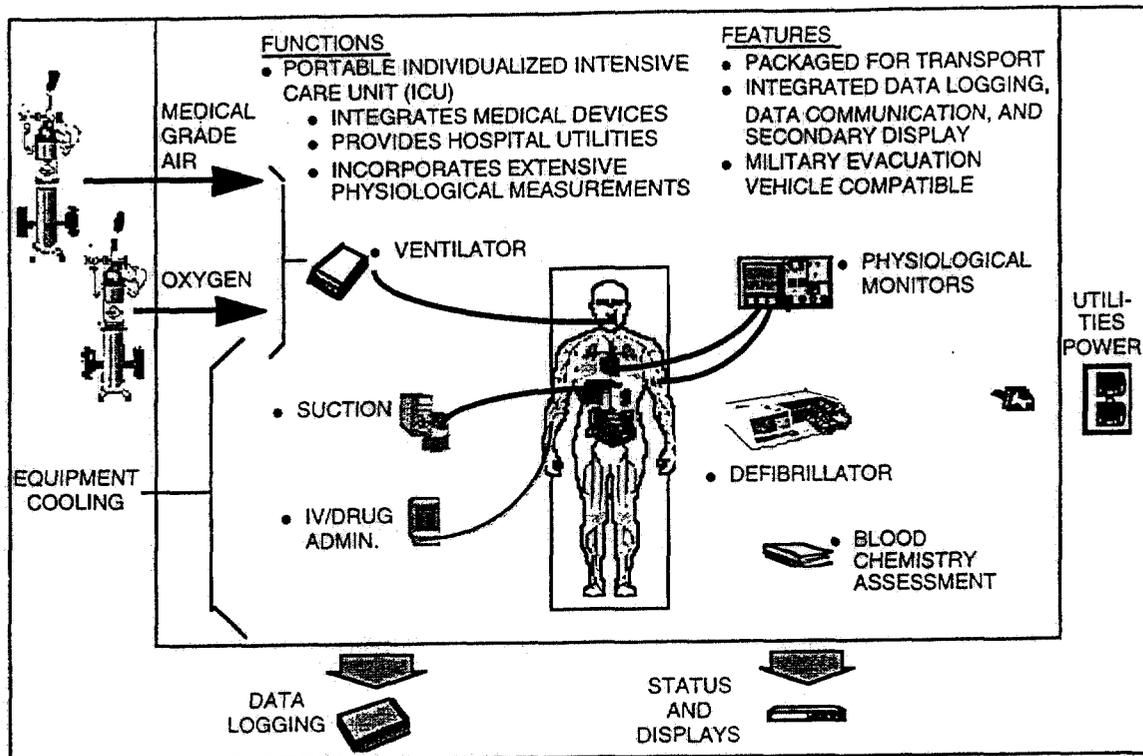
Common Name: Intensive Care Unit (ICU) Platform
Portable, Individualized ICU
Trauma Pod
Medical Evacuation Platform

Classification Name: (This Integrated System Category is Not Listed in 21 CFR
Parts 862-892.)

Device Description

The LSTAT Model 9601 is a portable individualization intensive care unit that incorporates resuscitative and life-sustaining medical devices within a single composite structure assembly.

The LSTAT functionality is shown in Figure 16-1 as a well equipped ICU bed.



96-091-007

Figure 16-1. LSTAT Model 9601: General ICU Functionality

Physically, the LSTAT Model 9601 is a highly instrumented patient transport platform (interfaced to a NATO litter) with medical devices incorporated within its composite structure assembly. Figure 16-2 shows the appearance of the LSTAT assembly whose unique outer moldline and low profile are defined for military transport compatibility (height = 13.2 inches, length = 86.8 inches, and width = 23.0 inches without patient). Device interfaces are collocated to favor awareness and controls in the "anestheologist position" during intra-operative procedures.

The LSTAT incorporates six portable patient monitoring/treatment subsystems/capabilities and five utilities/support subsystems as identified below.

The LSTAT **Medical Subsystems** include:

1. Physiological Monitoring

- a. ECG
- b. NIBP
- c. Invasive Blood Pressure (BP) (two channels)
- d. Temperature

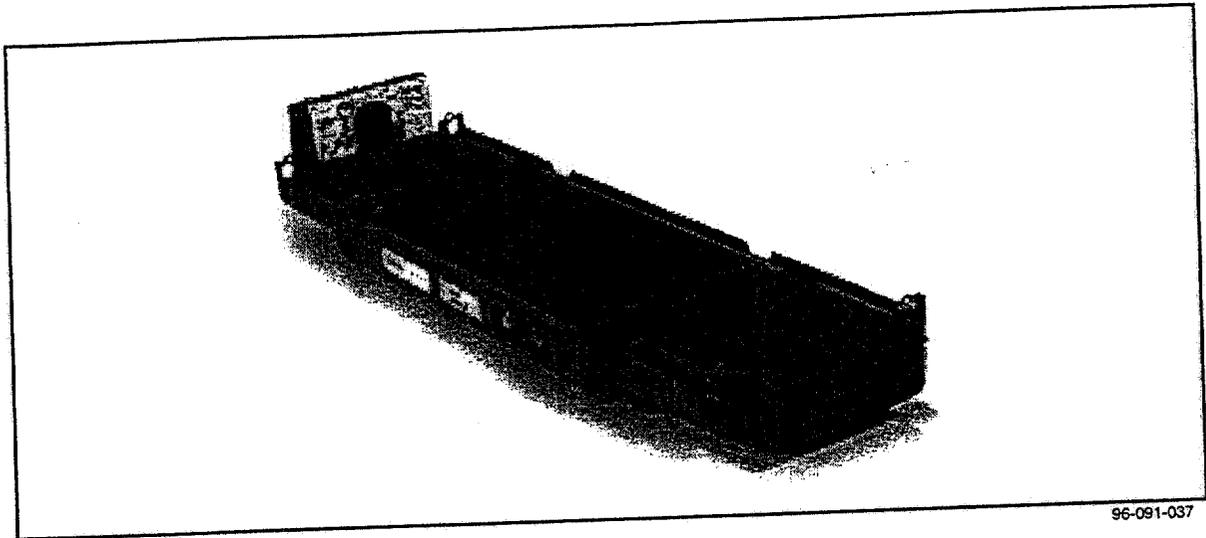


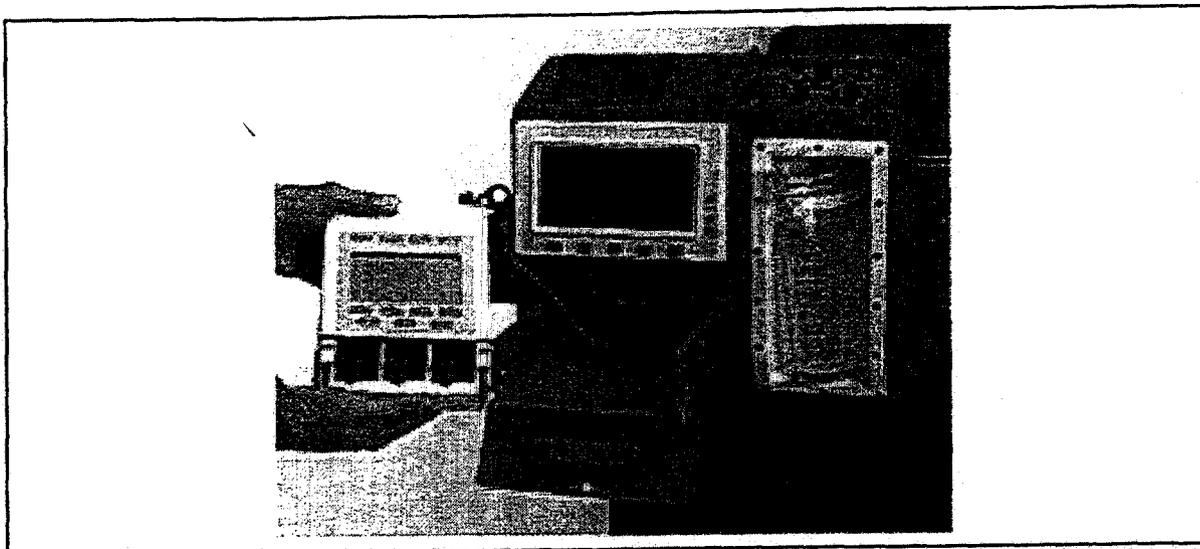
Figure 16-2. LSTAT ICU Platform Model 9601

2. Blood Chemistry Assessment (in vitro)
3. Suction
4. Automated External Defibrillator (AED)
5. IV Fluid Administration (and IV drugs)
6. Ventilator
 - a. On-board compressor (for medical air only)
 - b. Oxygen-air blending
 - c. Patient ventilation (controllable: mandatory or assist)
 - d. Ventilation assessment: airway pressure, airway $p\text{CO}_2$ and $E_t\text{CO}_2$, airway flow and tidal volume, and oxygen saturation (pulse oximeter)

The LSTAT Utilities/Support Subsystems include:

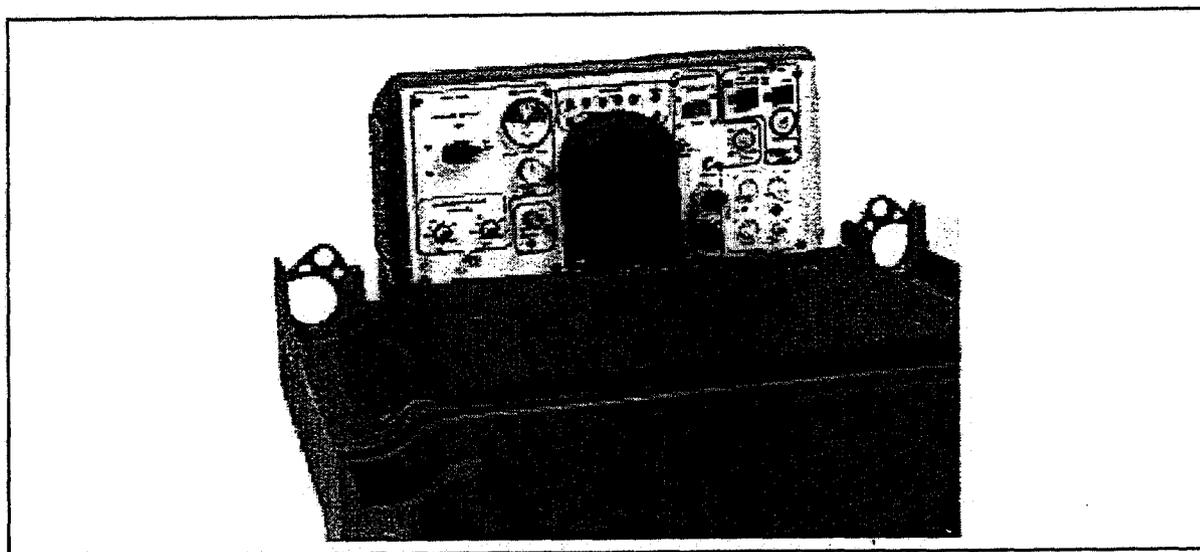
7. Structure (including NATO litter)
8. Oxygen
9. Electrical Power
10. Environmental Control Subsystem (ECS)
11. Data Logging and Display Subsystem (DDL) including a secondary display

Figure 16-3 illustrates the anesthesiologist's intra-operative position. Figure 16-4 illustrates the operator-patient interface panel where most of the patient connections to the LSTAT are made.



96-091-010

**Figure 16-3. Anesthesiologists Intra-Operative Position
(Control and Display Cockpit)**



96-091-011

Figure 16-4. Operator-Patient Interface Panel (Patient Connections)

Indications for Use: Medical Applications

The LSTAT Model 9601 is used to support resuscitation, stabilization, and transport of adult trauma victims or patients needing physiological monitoring and treatment capabilities of a hospital intensive care unit or trauma care unit for pre-operative, intra-operative, and post operative support during pre, intra, and post-transport phases.

The indications for use of selected subsystems/capabilities are dictated by medical protocol, but in general LSTAT use may be anticipated for victims of: combat/civilian casualty, trauma, respiratory distress, pneumothorax, severe fluid loss, cardiac emergency, or unstable clinical presentation.

Of course, the LSTAT may be used for transport of less severely injured or traumatized individuals which may not require the use of all the ICU subsystems.

Indications for Use: Transportation Applications

The LSTAT serves as a transportation platform which integrates existing medical devices and the NATO (STANAG) litter into a form-factor small enough to be loaded/carried within the constraints of military evacuation/transport vehicles like:

- UH-60 Blackhawk helicopter
- UH-1 Huey helicopter
- CH-47 Chinook helicopter
- C-9 aircraft
- C-17 aircraft
- C-130 aircraft
- C-141 aircraft
- MK-II Humvee ground ambulance
- Carrier, litter wheeled, (US Army).

Of course, other evacuation/transport vehicles (military or civilian) which do not impose the small (and customized) form factor or which are less densely loaded may also use the LSTAT.

Safety and Efficacy Discussions

The LSTAT provides for the safe transport, physiological monitoring, and treatment of trauma victims/patients without compromising efficacy by integrating FDA cleared medical devices and aerospace developed technologies for operation in severe environments.

The LSTAT is an integrated medical system whose design includes providing ICU functional capabilities, packaging devices for transport, data logging integration, and military evacuation vehicle/environment compatibility. Its safety and efficacy are based on:

1. Integration of existing legally marketed medical devices which have FDA clearance without change to their functionality, capability, controls, operator interfaces, or patient interfaces

2. Provision of utilities and support which meet the requirements of each device's operation
3. Continuous logging of both patient data and system/device data and alarms for redundant messaging of alarms and for support of post-treatment analysis of any event or observation (24 hours operations before down-load required with continued monitoring during down-load)
4. Aerospace designs for structure, severe environment operations, and airworthiness qualifications.

Device Equivalentents

The LSTAT incorporates six patient monitoring/treatment subsystems which contain medical devices which are summarized in Figure 16-5 with their FDA Class type. All devices except the ventilator are currently marketed by their respective suppliers. The ventilator is a customized, integrated subsystem developed for LSTAT. That subsystem incorporates multiple components of devices already legally marketed into its integrated design.

Subsystem	Class
- Physiological Monitoring	II
- Blood Chemistry	II
- Suction	II
- Defibrillator	III
- IV and Drug Administration	II
- Ventilator	II

Figure 16-5. Patient Monitoring/Treatment Subsystem

The listed devices are not just equivalent by predicate reference; they are equivalent by identity. The LSTAT integration design has not changed any of the supplier's circuitry or patient/operator interfaces. The modifications (discussed below) made to the devices have been to accommodate their integration into the low profile structure and to ensure that the devices will be operational in the severe military/transport environments.

Device Modification Enhancements

Minor repackaging of medical devices for severe operational environments and provisions for on-board utilities are the basic modifications and enhancements for medical devices contained within the LSTAT Model 9601.

The primary modifications made to the marketed devices have been to:

1. Disassemble them
2. Assemble multiple components onto shock mounts
3. Cluster patient connections and operator controls for "cockpit-like" interface
4. Locate components to maintain low profile within the composite EMI-protected structure
5. Provide environmental control
6. Provide centralized power sources, distribution, and support for all components (without preferential supply or denial of resources)
7. Provide communications with devices for data logging, analysis, and alarms.

System Integration Enhancements

The integration approach serves to offer several enhancements as a system:

1. Power: Centralization of power utilities permits all devices to be operated from multiple auxiliary (external) power sources and permits single cabling to their respective interfaces:

115 VAC +/- 10%	60 Hz +/- 5 Hz 1 phase
230 VAC +/- 10%	50 Hz +/- 3 Hz 1 phase
108-118/200 VAC	400 Hz +/- 7 Hz any phase
25 +/- 5 VDC	

and to provide un-interruptible backup power capabilities to all devices in the event of loss of auxiliary power. The rechargeable battery source also supports stand-alone operations (at least 30 minutes) during movement between locations while auxiliary power is unavailable. With the centralized subsystem, the need to manage recharge/replacement of each subsystem's batteries individually is eliminated and readiness of all devices concurrently is ensured. No software controls are used in the EPS which could provide power or operations to one

device preferentially over another. All power switching is under operator control and hardwired/circuit logic.

2. Data Logging and Display: Continuous data logging of patient and system data/status (including all real-time patient parameter waveforms) supports post event analyses of trauma physiology and system operation (flight data recorder equivalency). A secondary display, which is a portable computer, tethered, and capable of displaying any of the subsystems-reported data/alarms via real-time, ethernet communications is provided. This display permits the patient (or system) status to be presented at any location around the LSTAT structure thereby permitting the operator (or observer) to receive information even if the primary device display is not accessible during transport (or operative) scenarios. This secondary display could also include capability for wireless transmission of the data.
3. Environmental Control: Accommodations for equipment cooling and temperature are provided. Electromagnetic interference (EMI) protection is provided for control of emanations and electromagnetic susceptibility (EMS).
4. Structural Support: The structure provides the physical support for the patient and components within a lightweight composite housing which interfaces with the Blackhawk's carousel pan and other military evacuation vehicles identified above. The structure locks the NATO litter (which is assumed to be the way the patient is brought to the LSTAT) in place thereby eliminating the need to move the patient between platforms. The physical mounting of the internal components are designed to accommodate the vibration, shock, and rugged environments anticipated. The structure provides monitoring of tilt, acceleration, humidity, ambient temperature, and altitude and includes this information in the data logging records being generated.
5. Oxygen: Compressed and regulated oxygen (480 liters) is provided for controlled blending with ambient air to administer oxygen enriched air through the ventilator or through a mask/cannula.

Safe Design Analysis

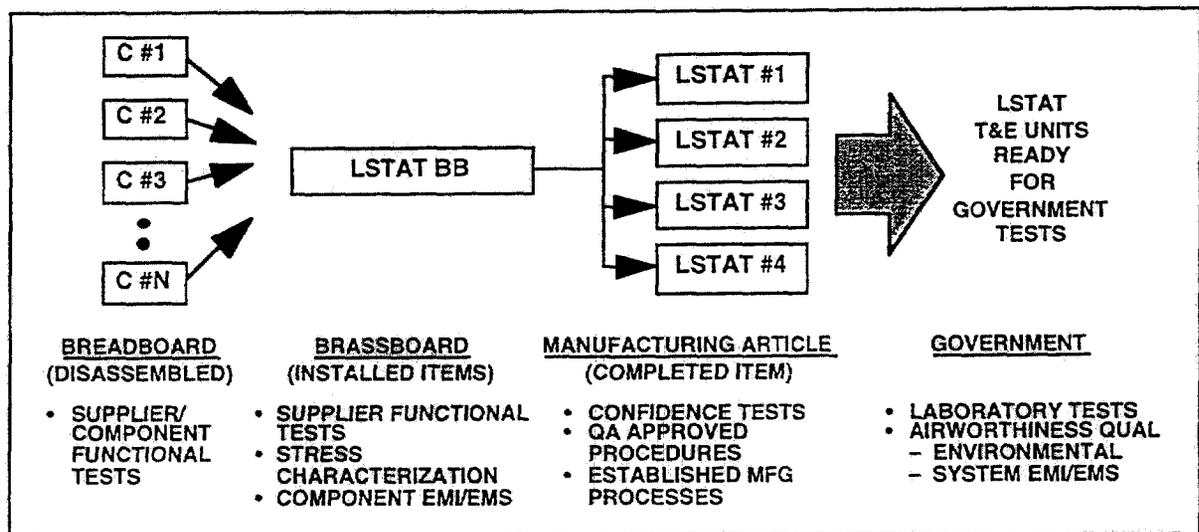
Aerospace qualified safety engineers provide analysis and acceptance validation of the LSTAT modification designs, implementations, and hazard analyses (see Hazard Analysis in Appendix A). Supplier hazard analyses were included to ensure no modification created or impacted existing device hazard mitigation, and NGC hazard

analysis and mitigation assured that no NGC design or implementation produced unacceptable patient or operator hazard.

Test Program

A comprehensive test program is in place to evaluate devices and total LSTAT assembly for integrated functionality (in vitro subsystem acceptance testing per suppliers directions), stress characterization (vibration, shock, thermal, and altitude), component and system EMI/EMS, manufacturing acceptance tests, usability tests, and airworthiness qualifications.

Figure 16-6 illustrates the series and sequence of testing addressed in the Test Plan.



96-091-039A

Figure 16-6. System Level Validation

The design to operating temperature ranges for many pieces of equipment and parts are -26°C to +49°C. Some medical displays and fluid handling capabilities may be limited at 0°C.

U.S. Government Laboratories (WRAIR, USAARL, and Brooks AFB) are participating with Northrop Grumman engineers/technicians in the validation/verification of safety and efficacy.

Several of the incorporated devices have been through airworthiness qualification testing at USAARL as separate devices: physiological monitor, suction, defibrillator, and IV infusion pump.

Conclusion

The LSTAT integration of legally marketed medical devices into a portable, individualized, intensive care unit has maintained the safety and efficacy of the existing devices and provided utilities and support for their operations which have passed the rigors of aerospace design and development. The safety and efficacy of the LSTAT system in military and airborne environments will be asserted by the U.S. Government and tracked with analysis of the extensive data logging capability of each device.

The above 510(k) Summary accurately reflects the information as submitted in other portions of this application.

If you have any questions, please direct them to the undersigned at (310) 948-8628 or Fax at (310) 942-3726.

Sincerely,



Nat F. Piscitelli, Director
Business Management and Operations
Northrop Grumman Corporation
Advanced Technology and Development Center



JUN 26 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Louis S. Toth, Ph.D.
Northrop Grumman Corporation
Military Aircraft Systems Division
Advanced Systems and Technology
Department N800/XA
8900 East Washington Boulevard
Pico Rivera, CA 90660

Re: K965117
Life Support for Trauma and Transport
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: April 24, 1998
Received: April 28, 1998

Dear Dr. Toth:

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 legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for

Page 2 - Louis S. Toth, Ph.D.

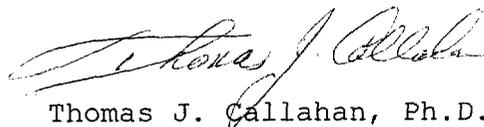
devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993, Federal Register beginning on page 43447.

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/dsma/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

Enclosures

