K070034

SECTION 5: 510(k) SUMMARY

AUG 17 2007

Submitter: Ascent Healthcare Solutions
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Phoenix, Arizona 85044

Contact: Katie Bray
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Date of preparation: December 29, 2006

Name of device: *Trade/Proprietary Name:* Reprocessed Cardiac Stabilization and Positioning Devices

Classification Name: Cardiovascular surgical instruments

Predicate Device	510(k) Title	Manufacturer
K992833	Vacuum Assist Stabilizer	CardioThoracic Systems (Guidant)
K982419	CTS Heart-Lift Balloon Positioner	CardioThoracic Systems (Guidant)

Note: These are class I devices that do not require a 510(k) for original (brand new) devices. Therefore, the predicate device may not have a filed 510(k) from the original manufacturer.

Device description: Cardiac stabilization and positioning devices are specially designed devices used in minimally invasive cardiac surgery for coronary artery bypass grafting. The devices offer a retraction as well as a stabilizing function to control the movement of the beating heart. The cardiac stabilization and positioning devices consist of a combination of one or more of the following components: tissue stabilizer, heart positioner, and sternum retractor blades.

Indications for Use: Reprocessed Cardiac Stabilization and Positioning Devices are indicated for use during performance of minimally invasive cardiovascular surgery through a sternotomy incision approach on the non-arrested heart. Sternum retractor blades are used to provide access to the thoracic cavity and to provide a mount for the tissue stabilizer and heart positioner. It also facilitates the positioning of pericardial sutures. The tissue stabilizer is used to stabilize and minimize the motion of selected sites on the beating heart. The heart positioner aids in positioning the heart by the application of vacuum suction when positioned on the heart.

Technological characteristics: The design, materials, and intended use of Reprocessed Cardiac Stabilization and Positioning Devices are identical to the

predicate devices. The mechanism of action of Reprocessed Cardiac Stabilization and Positioning Devices is identical to the predicate devices in that the same standard mechanical design, materials, and size are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Ascent Healthcare Solutions's reprocessing of Cardiac Stabilization and Positioning Devices includes removal of adherent visible soil and decontamination. Each individual Cardiac Stabilization and Positioning Device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Cardiac Stabilization and Positioning Devices. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Cardiac Stabilization and Positioning Devices perform as originally intended.

Conclusion: Ascent Healthcare Solutions concludes that the modified devices (Reprocessed Cardiac Stabilization and Positioning Devices) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Ascent Healthcare Solutions
c/o Ms. Katie Bray
Regulatory Affairs Engineer
10232 South 51st Street
Phoenix, AZ 85044

Re: K070034
Reprocessed Guidant (CTS) Cardiac Stabilization and Positioning Devices
Regulation Number: 21 CFR 870.4500
Regulation Name: Cardiovascular Surgical Instruments
Regulatory Class: Class I non-exempt
Product Code: NQG
Dated: July 20, 2007
Received: July 23, 2007

Dear Ms. Bray:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

ProCode	Family	Model
NQG	Guidant Heart Stabilizers and Positioners	Ultima Std Foot Stabilizer (OM-2001)
		Ultima Mechanical Stabilizer with Std Blades (OM-2001S)
		Ultima Mechanical Stabilizer Left Offset w/Std Blades (OM-2003S)
		Acrobat Mechanical Stabilizer w/Std Blades (OM-6000S)
		Acrobat SUV Vacuum Stabilizer (OM-9000)
		Acrobat V Vacuum Stabilizer (OM-9100)
		Acrobat SUV Vacuum Stabilizer w/Std Blades and Tubing (OM-9000S)
		Xpose 3 Access Device (XP-3000)
		Xpose 4 Access Device (XP-4000)
		AccessRail Standard Blade Platform (SB-1000)

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070034

Device Name: Reprocessed Guidant Cardiac Stabilization and Positioning Devices

Indications For Use:
Reprocessed Cardiac Stabilization and Positioning Devices are indicated for use during performance of minimally invasive cardiovascular surgery through a sternotomy incision approach on the non-arrested heart. Sternum retractor blades are used to provide access to the thoracic cavity and to provide a mount for the tissue stabilizer and heart positioner. It also facilitates the positioning of pericardial sutures. The tissue stabilizer is used to stabilize and minimize the motion of selected sites on the beating heart. The heart positioner aids in positioning the heart by the application of vacuum suction when positioned on the heart.

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 Cardiovascular Devic
510(k) Number K070034