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**FOR IMMEDIATE RELEASE**

**ASCENT HEALTHCARE RECEIVES 510(K) CLEARANCES TO REPROCESS  
CORONARY BYPASS DEVICES FROM GUIDANT AND MEDTRONIC**

**Phoenix, Ariz. – Oct. 8, 2007** – Ascent Healthcare Solutions, announced today that the U.S. Food and Drug Administration (FDA) has cleared two Ascent 510(k) submissions to reprocess specific Medtronic and Guidant cardiac stabilization and positioner devices.

The Medtronic models include the Octopus® Evolution Tissue Stabilizer (as well as the other predecessor Octopus models), Starfish® and Urchin® Heart Positioners. Guidant models covered under this clearance include the complete line of vacuum and mechanical systems: Xpose, Ultima and Acrobat systems. Ascent is the only company with clearance to reprocess the 10<sup>th</sup> generation Octopus Evolution Tissue Stabilizer and all the Guidant models. The devices are mainly used in Off-Pump Coronary Artery Bypass (OPCAB) or “beating heart” procedures. Approximately 350,000 U.S. patients undergo coronary bypass grafts annually. Currently, about 25 percent of the general population cases are being performed off-pump.

According to Rick Ferreira, chief operating officer of Ascent, “Using a reprocessed device can reduce OPCAB procedure costs by \$1,200 while maintaining the superior performance of the device. That not only helps keep healthcare costs lower, but also diverts waste from our overtaxed landfills.” He added that a typical 250-bed hospital performing 100 procedures with OPCAB devices could save an average of \$60,000 to \$100,000 a year and redirect approximately 65 pounds of equipment away from disposal sites.

Devices were subjected to a proprietary multi-step cleaning process to render them as safe for use as all the appropriate considerations for disinfection and sterilization are applied in the design, development and implementation of the reprocessing system. As part of the rigorous functional verification validation processes reviewed by the FDA, these devices underwent a battery of performance tests during simulated use, checking factors such as mechanical, fatigue, tensile and suction-pressure and integrity to ensure that the reprocessed devices will function as intended. For instance, certain components, such as the locking mechanism and articulating arm, were subjected to mechanical and fatigue testing, while the positioners and stabilizer feet were tested to ensure suction pressure.

Ascent's reprocessed Guidant and Medtronic OPCAB devices meet the requirements in order to qualify and carry labeling as "non-pyrogenic." "Pyrogens" are fever-causing byproducts of gram negative bacteria or endotoxins. Ascent accomplished this level of cleanliness by removing bacterial endotoxins to less than 20 EU (endotoxin units) per device, which is achieved in a final rinse process using reverse osmosis/de-ionized water. (Acceptable cleanliness limits are derived from United States Pharmacopeia standards.) Ascent has been successfully reprocessing these devices prior to FDA's reclassification for many years.

Previously, this device category was classified as "Class 1 exempt," meaning the devices did not need a pre-market clearance for reprocessing. But after a routine, periodic review, the FDA reclassified the models as "Class 1 non-exempt," meaning the 510(k) process applied to reprocessed Cardiac Stabilization Devices for the first time.

"We are pleased that our hospital partners will continue to realize the benefits of reprocessing these devices — significant cost savings and a reduction in medical waste — without interruption despite the reclassification," said Ferreira. "We look forward to saving our hospitals even more money now that Ascent has achieved the first clearance for the popular Evolution model."

### **About Ascent Healthcare Solutions**

Since its inception, Ascent Healthcare Solutions, the leading independent third-party reprocessor of single-use medical devices (SUDs), has reprocessed more than 50 million SUDs, saving its customers in excess of \$500 million in supply expenses and eliminating over 10,000 tons from local landfills. Ascent's 1,700 hospital partners include most of

the U.S. News and World Report “Honor Roll” hospitals. The company has agreements with all leading national group purchasing organizations as well as numerous nationally recognized hospital integrated delivery networks. The company has also been recognized as a “Champion for Change” by Hospitals for a Healthy Environment (H2E) in recognition of the dramatic environmental benefits reprocessing by Ascent provides to U.S. hospitals and surgery centers. For more information about Ascent Healthcare Solutions, visit [www.ascenths.com](http://www.ascenths.com).

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