



MEMORANDUM

TO: Ascent Customers

FROM: Ascent Healthcare Solutions, Regulatory Affairs

RE: Open/Unused Product and Regulations

DATE: July 26, 2007

This memo is to address the regulations pertaining to Ascent Healthcare Solutions and the handling of open/unused product re-sterilized at Ascent Healthcare Solutions.

Ascent Healthcare Solutions (Ascent) is registered with the FDA as a medical device manufacturer. We are regulated by Title 21, Code of Federal Regulations, Section 820, Quality System Regulation, which is the same regulation imposed on original equipment manufacturers. We are required to have a documented quality system in place, which requires that we have written procedures for all aspects of the reprocessing operation, from receipt through sterilization and shipping. We validate our equipment and processes through installation/operational and performance qualifications. Sterilization validations are performed on each of our sterilizers annually.

Open/unused does not constitute a "class" of medical devices. The FDA determines the class of a device. The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The three classes and the requirements that apply to them are:

- Class I General Controls
- Class II General Controls and Special Controls
- Class III General Controls and Premarket Approval

Only specific Class I and Class II devices are re-sterilized by Ascent through the Open/unused program. No Class III devices are re-sterilized by Ascent. Open/unused devices re-sterilized at Ascent Healthcare Solutions are processed using the same documented quality system and validated sterilization processes as all other product that is reprocessed by Ascent. Open/unused devices are re-sterilized by Ascent using a validated Ethylene Oxide sterilization method. Our Sterility Assurance Level for our open/unused and reprocessed devices is 10^{-6} . Our Sterility Assurance Level ensures that the open/unused devices re-sterilized by Ascent are safe for patient use.