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ATEK Medical Receives ISO-13485:2003 Certification and FDA Registration for Costa Rica Manufacturing Facility

*Recognizing the highest standards of quality, the ISO certification and FDA approval affirms
ATEK's ability to serve client manufacturing and distribution needs*

GRAND RAPIDS, MICH. (Oct. 3, 2008) – [ATEK Medical](#), a division of [ATEK Companies](#), announced today that its new 33,000-square-foot medical device manufacturing facility in Heredia, Costa Rica is [ISO-13485:2003](#) certified and is also registered with the [Food and Drug Administration](#) (FDA).

The ISO 13485:2003 certification is based on an inspection earlier this year by [TUV America](#) and demonstrates ATEK Medical's continuing commitment to international quality management system standards.

“At ATEK, we have always been committed to excellence,” said Chris Oleksy, president, ATEK Medical. “The ISO certification and FDA registration demonstrates that our focus — whether in Grand Rapids or Heredia — remains on quality, world-class performance and continuous monitoring of our business operations. This commitment ensures that we deliver on the promises we make to our clients and in turn that our clients make to their customers.”

Located 9 miles or about 14 kilometers north of San José in a Free Trade Zone, ATEK Medical's Costa Rica facility specializes in Class II single-use and electro-disposable device, and Class III implantable device manufacturing. All aspects of the facility were designed for compliance to ISO-13485 standards for medical device production. The facility opened in October 2007 and will soon be at full operating capacity.

“From the initial phases, we worked very hard to prepare our facility for the ISO auditing process,” said Jorge Vargas, Costa Rica general manager, ATEK Medical. “The certification was a critical milestone for our operations. We are proud that we were able to gain our ISO certification in a short period of time – it is a testament to our commitment and expertise.”

Developed by the [International Organization of Standards](#), ISO 13485:2003 is a stand-alone medical device quality system standard specifically intended for the medical device industry focusing on regulatory quality system requirements. Published in 2003, the standard represents the requirements for a comprehensive management system for the design and manufacture of medical devices.

For additional information about ATEK Medical, please visit www.atekmedical.com

About ATEK Medical

ATEK Medical is a total solutions partner serving the medical, disposable, electro-mechanical and implantable device markets. From product design and launch to distribution and post-production fulfillment, the ATEK Medical team is dedicated, skilled and cross-trained to serve your company's needs. ATEK Medical capabilities include product development and launch; medical device manufacturing; packaging, labeling and sterilization services; microbiology services; supply chain management; and post-production fulfillment services. ATEK Medical is ISO 13485:2003 certified and FDA registered to design, produce and launch Class I, II and III medical devices. Since 1979, ATEK Medical has developed and launched more than 300 unique products and specializes in product management and full-service manufacturing. For more information on ATEK Medical, visit www.atekmedical.com

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