SoundBite™ Hearing System Receives FDA Clearance for Treatment of Single Sided Deafness

Sonitus Medical, Inc., a medical device company that manufactures the world’s first non-surgical and removable hearing prosthetic to transmit sound via the teeth, today announced that it has received FDA clearance for its SoundBite Hearing System. The FDA 510(k) clearance is the first for the company and the product.

San Mateo, CA (PRWEB) January 28, 2011 -- Sonitus Medical, Inc., a medical device company that manufactures the world’s first non-surgical and removable hearing prosthetic to transmit sound via the teeth, today announced that it has received FDA clearance for its SoundBite Hearing System. The FDA 510(k) clearance is the first for the company and the product.

“We are thrilled to have achieved this major milestone both for the company and for the many patients who stand to benefit from our novel device,” said Amir Abolfathi, CEO of Sonitus Medical. “Over the coming months, we look forward to introducing the product to the US market in partnership with Otologists and ENT physicians with an Audiology practice with a focus on good clinical practice and giving patients with single sided deafness the choice of a new and non-surgical treatment option.”

The SoundBite Hearing System was found to be safe and effective in two pivotal clinical trials, which supported the FDA clearance. One study evaluated the safety and efficacy of the SoundBite system over a period of one month in 28 patients. Results of this study have been accepted for publication in a future issue of the well-respected Otology and Neurotology professional journal. A second study evaluated the long-term safety of the device over a six month period in 22 patients.

Principal Investigator for the studies was Michael Murray, M.D., an Otologist with Camino Ear Nose and Throat of San Jose, CA. “My patients were extremely happy with the SoundBite system in terms of how well it addressed their hearing problem without requiring them to undergo an invasive surgery” said Dr. Murray. “This new approach gives me a great new treatment option for my patients with single-sided deafness. Patients who until now have chosen to go untreated due to the lack of an acceptable alternative.”

Key safety and efficacy measures evaluated in the studies included the SoundBite system’s benefit and impact on auditory performance, improvement in speech intelligibility, oral health, and overall comfort. Findings included:

- 95% of patients were either satisfied or very satisfied with the performance of the SoundBite device in terms of addressing their hearing problem after six months of wear, and 95% were also either likely or very likely to recommend the device to a friend who had the same hearing problem as theirs;

- The device was found to be safe for long-term use as there were no medical, dental, or audiological product- or procedure-related adverse events after six months wear of the SoundBite system.

- The removable In-The-Mouth (ITM) device showed no long-term effects on dental or periodontal soft or hard tissues and was determined to be safe for long-term dental wear. The device was worn on patients’ natural teeth, as well as on those with fillings, restorations, crowns, root canals, and dental implants.
About SoundBite
SoundBite hearing system is the world’s first and only non-surgical and removable hearing solution designed to imperceptibly transmit sound via the teeth to help people who are essentially deaf in one ear regain their spatial hearing ability and rejoin the conversation of life. It employs a well-established principle called bone conduction to deliver clear, high quality sound to the inner ear. Nearly invisible when worn, the SoundBite system consists of an easy to insert and remove ITM (in-the-mouth) hearing device—which is custom made to fit around either the upper left or right back teeth—and a small microphone unit worn behind the ear. No modifications to the teeth are required. This system currently has FDA 510(k) clearance to treat single sided deafness. Intended future indications include conductive and mixed hearing loss.

About Sonitus Medical
Sonitus Medical Inc. is a privately held medical device company developing the SoundBite hearing system, a non-surgical and removable hearing solution that imperceptibly transmits sound via the teeth. Relying on the principle of bone conduction, this nearly invisible ITM (in-the-mouth) hearing and communication platform is currently for investigational use only and is initially intended as a simple and non-invasive treatment for hearing disorders such as single sided deafness, conductive and/or mixed hearing loss and tinnitus. Potential future applications include consumer and covert communications. Founded in June 2006, Sonitus Medical is headquartered in San Mateo, California. To learn more about Sonitus Medical, please visit www.sonitusmedical.com.

Press Contact:
Jason Shelton, VP Marketing
Sonitus Medical, Inc.
(650) 353-5827

SOURCE: Sonitus Medical, Inc.

###
Contact Information
Jason Shelton
Sonitus Medical, Inc.
http://www.sonitusmedical.com
(650) 353-5827

Online Web 2.0 Version
You can read the online version of this press release here.