Dental hearing aid receives European CE Mark certification

SAN MATEO, CA, USA: A very unusual hearing aid, which is placed inside the mouth, is about to find its way into the European market. The device, called SoundBite, is manufactured by American medical device company Sonitus Medical. It is custom made to fit around either the upper left or right molars.

According to the manufacturer, the new hearing system is designed to allow sound to travel via the teeth, through the bones, to both cochleae, bypassing the middle and outer ear entirely. By using bone conduction via the teeth, SoundBite is intended to restore normal hearing to patients with single sided deafness, conductive or mixed hearing loss, all without surgery.

“It is not yet available in Europe. However, we have obtained CE approval to market the device in Europe. We are still determining the time frame,” Shirley Guerrero, Marketing Specialist at Sonitus Medical, told Dental Tribune ONLINE. According to the European Commission, products hearing the CE marking are presumed to be in compliance with the applicable directives and hence benefit from free circulation in the European Market.

Nearly invisible when worn, the system consists of an easy to insert and remove In-The-Mouth hearing device and a small microphone unit worn behind the ear. No modifications to the teeth are required.

The hearing device was reviewed in the April issue of the journal Otology & Neurotology and found to be “a safe and effective system, which provides substantial benefit for SSD patients with continual daily use over a 30-day period”. According to the authors of the review, no medical, audiologic or dental complications were experienced.

However, critical reception of SoundBite has not only been positive. In a BBC News article, Angela King, senior audio advisor at the Royal National Institute for Deaf People, expressed doubts over the significance of the new hearing device. “Just by looking over the significance of the new device and the system consists of an easy to insert and remove In-The-Mouth hearing device and a small microphone unit worn behind the ear. No modifications to the teeth are required.”

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J&J To Pay $10M to Girl Hurt By Motrin

A Pennsylvania state court jury has ordered Johnson & Johnson to pay $10 million in damages to the family of a 15-year-old girl who suffered skin burns and eye damage after she took Children’s Motrin to treat a fever and cough.

After deliberating for 10 hours over two days, the jury decided that J&J’s McNeil Consumer Products unit was liable for injuries suffered by Brianna Maya, now 15, who was left blind in one eye and suffered burns over 84 percent of her body. The injuries were sustained after she took Motrin in 2000, when she was 3-1/2 years old.

Her lawyer charged J&J didn’t include a warning that year alerting consumers the med can cause Stevens-Johnson Syndrome. J&J companies later warned that ibuprofen, the active ingredient, could trigger “a severe allergic reaction,” and the symptoms could include rashes and blisters. The girl’s family sought at least $5 million in damages to cover medical bills and other expenses.

J&J has faced at least two other jury trials over claims that links to Stevens-Johnson Syndrome, an allergic drug reaction that can leave patients with damaged eyes, a blistered mouth and burned skin, Bloomberg notes. In 2008, a California jury cleared J&J for injuries suffered by an 11-year-old girl who took the med and developed the syndrome; her family had sought $1 billion in damages. Two years later, a federal jury in Illinois awarded a woman who took Children’s Motrin and suffered similar injuries $3.5 million in damages. However, a judge threw that award out on procedural grounds.
Planmeca donates top-level dental devices to the dental clinic in Japan tsunami region

The Finnish company Planmeca Oy, one of the world’s leading dental equipment manufacturers, announces its donation of a Planmeca Compact i dental unit along with a Planmeca ProMax 3D s imaging unit to the temporary dental clinic that is being set up by the Japanese government and Japan Dental Association in the tsunami region.

“We found out that there are temporary dental clinics to be established in Tohoku region with the support of Japanese government. We would like to do our share in contributing to the rebuilding efforts of this tsunami-ridden region. With these dental devices modern, high-quality dental care become available for people in the crisis area,” says Mr. Heikki Kyöstilä, the president of Planmeca Oy.

The design of the Planmeca Compact i dental unit has been strongly steered by the importance of ergonomics and unpromised safety of the dental team as well as highest level of hygiene. There are over 25 000 Planmeca Compact i dental unit installations and users around the world.

Planmeca is the market leader in dental imaging devices – panoramic, intraoral and 3D imaging units – in the world. The Planmeca ProMax 3D s digital imaging unit is designed to obtain complete information on patient anatomy in the minutest detail. The unit complies with a multitude of diagnostic requirements: those of endodontics, periodontics, orthodontics, implantology, dental and maxillofacial surgery, and TMJ analysis. Planmeca ProMax 3D s unit is ideal for imaging with a smaller field of view: the imaging size is optimal for e.g. single implant and wisdom tooth cases, as well as for implant surgery and orthodontic treatment. “All Planmeca imaging units comply with the best practices of dentistry. Pulsed X-ray of 3D units, together with the short rotation scan, virtually eliminates artefacts, contributing to outstanding image quality. Planmeca’s patented, computer-controlled SCARA (Selectively Compliant Articulated Robot Arm) technology allows a variety of imaging programs,” states Mr Kyöstilä.

The announcement of this sizeable donation made in cooperation with Planmeca’s distributor in Japan, the GC Corporation, at the 18th International Congress of DentoMaxillofacial Radiology in Hiroshima 26–28 May, 2011. The temporary dental clinic is expected to be set up in Tohoku region in June.