



PRESS RELEASE

FDA 510(k) submission of 'SurfLink® Dental Implant' - an endosseous dental implant system - by NBMolecules®

Gland, VD, Switzerland – January 2012 – Nano Bridging Molecules S.A. (NBMolecules®), is a privately held Swiss Medical Device/Life Science Research and Development company, focusing on the development of breakthrough surface treatments for dental and orthopedic implants.

The company announced the filing of a 510(k) Premarket Notification with the U.S. Food and Drug Administration (FDA) for regulatory clearance of the company's endosseous dental implant 'SurfLink® Dental Implant'.

Improving biocompatibility of an implant surface is a long standing challenge in the medical field. Several approaches have been developed over the years consisting mainly of mechanical (e.g. blasting, machining and polishing), chemical treatments (e.g. anodisation and acid etching) and surface coating, e.g. hydroxyapatite.

Hydroxyapatite is a calcium phosphate compound which resembles human bone tissue. Calcium phosphate coated titanium implants have been shown to have a superior initial rate of osseointegration and faster bone tissue growth onto the implant surface. The surface of NBMolecules® SurfLink® Dental Implant is similar to that of hydroxyapatite coated implants, in that bio-mimicking phosphate-like groups are presented to the surrounding implant environment providing a favorable environment for cell colonisation.

"SurfLink® treated implant surfaces promises long-term implant stability over a wide pH range and hence avoids any of the shortcomings of today's calcium phosphate coatings such as degradation which leads to dissolution and delamination", explains NBMolecules® Chief Technical Officer and Co-founder Dr. Björn-Owe Aronsson.

The biomimetic properties of the SurfLink® treated surface will enable early bone formation on the implant surface, yield considerably greater bone-to-implant contact, enhance early and long-term biomechanical fixation and thus promise true osseointegration.

The 510(k) filing followed the CE marking (Directive 93/42/EEC on Medical Devices) obtained for its SurfLink® Dental solution (May 2011) which allows NBM to freely sell and distribute its products throughout the 28 countries of the European Economic Area. A 510(k) clearance will provide access to the US dental implant market estimated to about 26% of the \$3.4 billion worldwide market. Due to an ever ageing population, the dental implant market is also growing at an estimated 12 percent a year.

"The features of SurfLink® also gives rise to the exciting prospect of making implants available to patient groups that are today prevented from using them due to deficient bone quality", Dr. Aronsson continues.

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About SurfLink®

NBMolecules® SurfLink® technology has been developed over a period of 12 years by a multidisciplinary team from a number of renowned academic institutions including the University of Geneva, Ecole Polytechnique Fédérale de Lausanne, the University of Zürich and the University of Bern. This collaboration has given rise to a highly sophisticated surface treatment technology which offers a range of benefits not found in any other surface treatment.

About Nano Bridging Molecules SA

NBMolecules® SurfLink® technology is protected by patents owned by the University of Geneva and Ecole Polytechnique Fédérale de Lausanne. According to a license agreement entered with these two institutions, the university spin-off, privately held company NBMolecules®, established in 2002, owns the worldwide exclusive rights to full and unrestricted use, development and exploitation of the technology.

In 2008 NBMolecules® established new laboratories and an office in Canton de Vaud, Switzerland. It currently employs 6 people, has entered into over 65 contracts with research institutions and other external service providers, and continues to grow.

Contact & Information

For our latest news, please visit <http://www.nbmolecules.com/> or contact:

Björn-Owe Aronsson
Co-founder and CTO
Tel: + 41 (0) 22 354 00 54
cto@nbmolecules.com

◀ Nano Bridging Molecules SA

Rte Cité-Ouest 2
CH-1196 Gland
Switzerland

- ◆ Phone +41 (0)22 354 00 54
- ◆ Fax +41 (0)22 354 00 55
- ◆ E-mail info@NBMolecules.com