

## First FDA approval for HA<sup>nano</sup> Surface® on a spinal implant

**“This represents a major breakthrough on the US orthopaedic market for us,” says Magnus Larsson, CEO at Promimic.**

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**The first spinal device utilizing HA<sup>nano</sup> Surface to improve osseointegration has now been 510(k) approved by the FDA. Through partnership with Promimic, Cutting Edge Spine developed the EVOL SI Sacroiliac Joint Fusion System, which will be commercially launched later this year.**

The HA<sup>nano</sup> Surface has been in clinical use on the dental implant market for several years, showing faster integration between the bone and the implant. Promimic has established US operations, and is now entering the orthopedic market with multiple OEM partners.

“Cutting Edge Spine represents a perfect partner for Promimic, with their tradition of pioneering novel technologies and successfully bringing them to the market,” says Magnus Larsson.

HA<sup>nano</sup> Surface has proven to accelerate bone growth in over 30 in vivo and in vitro studies. Faster and stronger osseointegration has been demonstrated through biomechanical, histomorphological, and biological evaluations, in combination with over 150,000 clinical applications to date.

“In our quest to improve patient care, we wanted a bioactive solution to secure faster and better implant integration in SI fusion procedures. HA<sup>nano</sup> Surface was the obvious choice for us when we looked for an implant surface modification to achieve those goals,” says Randy Roof, CEO, President and Founder of Cutting Edge Spine.

Promimic will be exhibiting at the North American Spine Society (NASS) Annual Meeting in Chicago, IL, September 25-28, Booth #3901.

### **About**

Promimic has developed a state-of-the-art nanotechnology that mimics nature, making it possible to create a unique bioactive surface on any implant. HA<sup>nano</sup> Surface is a 20 nanometer (.02 micrometer) thin implant surface modification composed of crystalline hydroxyapatite (HA) particles, which have the same shape, composition, and structure as HA found in human bone.

Cutting Edge Spine, established in 2009, is a proven leader in organic development and commercialization of novel bioactive spinal implant systems focused on improving patient care while offering patients, payors, and providers an optimal fiscal value proposition.

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