



First 3D printed HA^{nano} Surface[®] modified implant gets FDA approval

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Innovasis receives first special 510(k) clearance for porous spinal interbody device with HA^{nano} Surface; represents the fourth implant material with the HA^{nano} Surface to receive FDA approval.

Promimic AB, the world's leading innovator in nano surface modification, is pleased to announce the recent Innovasis, Inc. special 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the first spinal interbody devices modified with HA^{nano} Surface. This was the first special 510(k) FDA approval of a device with HA^{nano} Surface, meaning that since the regulatory pathway is established, an expedited regulatory process can occur. This also marks the first approval of a 3D printed porous titanium implant modified with HA^{nano} Surface.

The newly approved Innovasis micro porous 3D printed titanium devices include the AxTiHA™ System, a standalone IBF device for Anterior Lumbar Interbody Fusion (ALIF) with up to 66% porosity, and the TxTiHA™ System, an IBF device for Transforaminal Lumbar Interbody Fusion (TLIF) with up to 61% porosity. Through modification with HA^{nano} Surface, bio-enhanced AxTiHA™ and TxTiHA™ fully maintain their micro porous properties, allows osseointegration, and are super hydrophilic, which can stimulate an osteoconductive integration process to promote faster and more direct bone on-growth to the implant.

“The product development efforts with Innovasis have been extremely positive and collaborative. Promimic is delighted that they chose our HA^{nano} Surface technology to further differentiate their product portfolio. With them and our other spine, orthopedic, and dental corporate partners, we are excited to further our mission of making HA^{nano} Surface the gold standard for osseointegration of surgical implants,” says Magnus Larsson, Promimic CEO.

HA^{nano} Surface has been evaluated in more than 30 pre-clinical studies testing a variety of implant materials and designs in different models. It was proven to increase anchoring strength in surface modified titanium implants by up to 35% in just 3 weeks. The results also show that HA^{nano} Surface up-regulates important bone marker proteins and improves new bone formation on titanium implant surface by 67% at 4 weeks.

For more information about HA^{nano} Surface, please visit <https://www.promimic.com/>. To learn more about the Innovasis AxTiHA™ and TxTiHA™ interbody fusion devices, please visit <https://www.innovasis.com>.

About

Promimic's HA^{nano} Surface creates a unique bioactive surface on any implant and has demonstrated faster and stronger osseointegration in over 30 in vivo and in vitro studies, with over 300,000 clinical applications to date. Promimic operates primarily in the United States, Europe, and South America, with offices in Gothenburg, Sweden and Austin, Texas. Current product applications include the dental, spine, total joint, extremities, and sports medicine implant markets.

Innovasis is a groundbreaking company engaged in the research, development, manufacturing, and marketing of spinal implant devices and related products. Innovasis offers a spinal product line with implants and instruments that address the major pathologies and focus areas of traditional spinal surgery.

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