

## **Innovasis receives 510k for first Stand-Alone ALIF System made from PEEK-OPTIMA™© HA Enhanced polymer**

*Innovasis' Ax™ Stand-Alone ALIF\* System offers the potential advantage of enhanced osteoconductivity*

**Salt Lake City, UT, April 28th, 2017 – Innovasis, Inc. is the first company to receive US FDA 510(k) clearance for a Stand-Alone ALIF\* System made from PEEK-OPTIMA™© HA Enhanced polymer from Invibio©. Designed for use in spinal-fusion procedures, the implantable Ax™ Stand-Alone ALIF System implants contain osteoconductive hydroxyapatite (HA) fully integrated into the matrix of the polymer and exposed on all surfaces of the body of the implant, including within the inner walls of the graft chamber.**

This is the second PEEK-OPTIMA HA Enhanced device marketed by the company. At the end of Q416, the company launched a PxHA a PLIF device made from the same material.

The Innovasis Ax Stand-Alone ALIF System is an intervertebral fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). The implant is used to facilitate fusion in the lumbar spine and is inserted using an anterior lumbar interbody fusion (ALIF) procedure.

The Ax Stand-Alone ALIF implant also features a tapered leading edge, which aids in implant insertion within limited anatomical space. It also features a slightly convex profile to match the anatomy of the spine and provide a stable anti-migration surface during the fusion process. The large graft cavity provides increased volume for autograft loading.

### **About Innovasis**

Innovasis, Inc. is a rapidly growing 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. Innovasis is fully committed to providing surgeons and distributors with training, support and excellent customer service, thus ensuring the establishment of a strong and long-term strategic partnership.

To learn more, interested parties may contact:

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