



Innovasis Announces Successful FDA Clearance for Opteryx Cervical Plate System

Utah-based Innovasis, a research, development and manufacturer of spinal implant devices, has received 510(k) clearance of the Opteryx Cervical Plate System by the United States Food and Drug Administration.

"This is good news for our company as we strive to be a recognized leader in the global spinal business by building intense customer loyalty and improving our products," said Martin Crous, Ph.D., Vice President of Sales and Marketing of Innovasis.

The Innovasis Opteryx Cervical plate System is indicated for stabilizing the cervical spine from C2 to C7 and is intended for use in anterior cervical fixation for the following indications:

- Degenerative Disc Disease (defined as neck pain of discogenic origin with degeneration of the cervical disc)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities of curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis, and/or
- Previous failed fusion

Other products already cleared by the FDA for Innovasis include the Le Forte System, the Excella-M and PEEK products.

Innovasis offers spinal product implants and instruments that address major pathologies and focus areas of traditional spinal surgery, including deformities, degenerative conditions; trauma and tumors, all of which can result in severe back pain and sometimes paralysis. Spinal implants are aimed at restoring mechanical and neurological function by readjusting vertebral positioning until bone fusion occurs. Founded in 2002, Innovasis is committed to providing surgeons with training, support and excellent customer service.

Innovasis

<http://www.innovasis.com>