



Innovasis Submits 'PEEK Box' System for FDA Clearance

SALT LAKE CITY, Aug. 3 -- Utah-based spinal implant company Innovasis recently submitted its "PEEK Box" System to the FDA for 510(k) clearance. The "PEEK Box" System will be used as a Vertebral Body Replacement within the spine. The Innovasis "PEEK Box" System is manufactured from PolyEtherEtherKetone (PEEK) with Tantalum ELI markers. PolyEtherEtherKetone (PEEK) is a material with an elasticity module (GPA) that is the closest to Cancellous Bone compared to Cortical Bone, Titanium or Stainless Steel implants.

Features and benefits of the "PEEK Box" system include: Variety of different shapes, proud angled tooth design on superior and inferior surfaces to resist migration, Bullet-shaped tip to assist in distraction, and parallel and lordotic-shaped with large central apertures for placement of bone graft. The Innovasis "PEEK Box" System had previously received 510(k) clearance as a Cement Restrictor but has recently been re-submitted to the FDA for clearance as a VBR (Vertebral Body Replacement) for Spinal indications.

According to Martin Crous, Ph.D. Vice President of Sales and Marketing, FDA 510(k) clearance for the "PEEK Box" System as a VBR is expected in the 3rd quarter of 2006.

Spinal implants are aimed at restoring mechanical and neurological function by readjusting vertebral positioning until bone fusion occurs. 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. Founded in 2002, Innovasis is committed to providing surgeons with training, support and excellent customer service, thus ensuring the establishment of a strong and long term strategic partnership.

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