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Zavation gets 510(k) Clearance of the Normandy VBR System

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Zavation, an employee-owned medical device company that designs, develops, manufactures and distributes medical device products has received 510(k) clearance from the FDA to market Normandy VBR System (Cervical and Thoracolumbar Expandable Corpectomy Cage).

The Normandy VBR System is an adjustable height vertebral body replacement device that is implanted into the vertebral body space to provide structural stability in skeletally mature patients following corpectomy or vertebrectomy.

The system is comprised of spacers of various sizes and options to fit the anatomical needs of a wide variety of patients.

The device can be adjusted to the required height after implantation.

The device is mechanically locked at the required height by means of a locking screw. Each spacer has an axial hole to allow autograft or allograft to be packed inside each spacer.

Protrusions on the superior and inferior surfaces grip the endplates of the adjacent vertebrae to resist expulsion. Components are manufactured from titanium alloy (Ti-6AL-4V) per ASTM F-136.

The Normandy VBR System is indicated for use in the cervical spine (C2-C7) and thoracolumbar spine (T1-L5) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, osteomyelitis, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in degenerative disorders.

The Normandy VBR System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, as an adjunct to fusion.

The Normandy VBR System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.