

Theken Spine goes to market

FDA asked to approve new vertebral replacement systems

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This could be a record year for new products at Theken Spine LLC in Akron - if all goes well.

The family of spinal and bone implant companies recently asked the Food and Drug Administration for clearance to sell four new vertebral replacement systems and a modified system used during minimally invasive spine surgery.

Theken Spine expects to submit a sixth product - a thoracic plate used to fuse vertebrae in the upper spine - for FDA clearance by mid-2007.

"That would be the most product launches we've ever had in one year, if all goes well," said Rachael Smith, marketing communications director for Theken Spine.

The new products would round out Theken Spine's offerings, enabling the company to sell more to surgeons who already use its products. The launches also could attract new distributors who want to represent more complete lines of spinal replacements, Smith said.

The five products submitted for FDA review are:

- Atoll Cervico-Thoracic Fixation System - A system made up of eight multifunctional instruments used to fuse vertebrae in the middle of the spine.
- Vu Mesh PEEK-Optima - A cage that holds the place of a vertebra and its adjacent discs after replacement surgery. This cage is made from a polymer.
- Vu e-POD PEEK-Optima Vertebral Body Replacement System - Another polymer cage used to replace vertebrae that is a different shape than Vu Mesh.
- x-POD Adjustable Vertebral Body Replacement System - An expandable titanium cage used to replace vertebrae, being positioned for the trauma and tumor markets.
- Coral Minimally Invasive System - A vertebral fusion system implanted during minimally invasive surgery that offers more types of bone screws than the company's existing Coral products.

"All of the products were well-received" during the recent American Academy of Neurological Surgeons convention in Washington, Smith said.

But the Atoll product got the biggest buzz. "We are very excited about this system hitting," Smith said.

Theken Spine expects to get FDA clearance for all the new products by mid-year, Smith said.

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