

Centinel Spine® Receives FDA Approval for 3 Additional prodisc® Cervical Total Disc Replacement Devices

PRESS RELEASE

For Immediate Release

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- Centinel Spine now has four PMA approved cervical Total Disc Replacement (TDR) devices, offering the broadest spectrum of solutions to address surgeon preference and individual patient anatomy.
- The variety of cervical TDR endplate configurations, coupled with the proven and well-documented prodisc® CORE technology, allows for optimization of implant fit and surgical outcomes.
- The newly approved prodisc C Vivo and prodisc C Nova products have extensive clinical usage outside of the U.S. since 2009.
- The prodisc technology is the most studied and clinically-proven TDR system in the world, validated by over 540 published papers.



prodisc. C Vivo

prodisc. C SK

prodisc. C Nova

West Chester, PA, July 13, 2022 – Centinel Spine®, LLC, a leading global medical device company addressing cervical and lumbar spinal disease through anterior surgical access, today announced U.S. Food and Drug Administration (FDA) Pre-Market Application (PMA) Approval for 1-level indications for three additional cervical total disc replacement (TDR) devices: **prodisc C Vivo**, **prodisc C Nova**, and **prodisc C SK**. Along with the currently available **prodisc C** implant, which continues to be widely used throughout the U.S., Centinel Spine now has the broadest offering of cervical TDR solutions in the world to address surgeon preference and individual patient anatomy.

The TDR market is expected to remain the fastest growth segment within the spine industry, growing globally in excess of 11% CAGR and reaching \$2.69B by 2026 (*Artificial Disc Market Insights, Competitive Landscape and Market Forecast-2027*, DelveInsight Business Research LLP, 2022). The **prodisc** platform has been a pioneering TDR technology and a major contributor to this growth with continuous innovation over the past 30 years. Centinel Spine is the only company offering multiple cervical TDR options for surgeons to select from based on each patient’s anatomy at the surgical level.

The **prodisc C Vivo** and **prodisc C Nova** products have been in use outside the U.S. since 2009, and **prodisc C Vivo** is currently the most frequently implanted TDR outside of the U.S. The **prodisc C Vivo** product has keel-less endplates including a convex, superior endplate to match more concave vertebral anatomy, while the **prodisc C SK** and **prodisc C Nova** implant designs have flat endplates with low-profile keels to better match flat vertebral anatomy. All of these products incorporate **prodisc CORE** technology, the basis behind the predictable clinical outcomes of every **prodisc** device after 30 years and over 225,000 implantations, worldwide.



“The FDA approval of the **prodisc C Vivo**, **Nova**, and **SK** devices offers the surgeon a new level of modularity and stability for cervical disc replacement,” says Jason Tinley, MD, orthopedic spine surgeon and founder of DFW Center for Spinal Disorders in Dallas-Fort Worth, TX. “The patient can now receive an implant that best conforms to their anatomy intraoperatively, with variable endplate characteristics that best suit the surgeon’s preference of technique,” Dr. Tinley adds.



Centinel Spine's CEO, Steve Murray, stated, "Anatomic cervical total disc options provide surgeons the benefit of selecting implants to optimally fit the disc to each patient. This is unique and represents a major advancement in spinal reconstruction. PMA approval for these three additional devices is a significant accomplishment and we look forward to bringing the new **prodisc** options to the market in Q4 2022."

Centinel Spine also continues to enroll for a two-level prospective, randomized, multi-centered clinical study evaluating **prodisc C Vivo** and **prodisc C SK**.

About Centinel Spine, LLC

Centinel Spine[®], LLC is a leading global medical device company addressing cervical and lumbar spinal disease through anterior surgical access. The company offers a continuum of trusted, brand-name, motion-preserving and fusion solutions backed by over 30 years of clinical success—providing the most robust and clinically-proven technology platforms in the world for total disc replacement (**prodisc[®]**) and Integrated Interbody™ fusion (**STALIF[®]**).

Centinel Spine continues to advance its pioneering culture and corporate mission to become a catalyst of change in the spine industry and alter the way spine surgery is perceived. Centinel Spine remains the only company with comprehensive motion-preserving and fusion solutions for both cervical and lumbar anterior column reconstruction.

For more information, please visit the company's website at www.CentinelSpine.com or contact:

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