



SanaVita Medical manages reverse-engineering, reduces time to clinical evaluation for **spinal tether implant**.

Challenge

A new novel treatment for pediatric scoliosis was hanging in the balance.

A global medical device company was working on developing a spinal tether implant as an alternative treatment to spinal fusion when the organization behind the technology folded. The move left the device company without the original product specifications or the team of experts that helped develop the technology.

With the clock ticking on an already tight market-launch timeline, the device company needed to find an organization that had the means to reverse-engineer the spinal tether implant and package the product for scheduled clinical evaluations.

Solution

The company's search for a new qualified partner didn't last long.

The client contacted SanaVita Medical, an FDA-registered contract manufacturing organization (CMO) with flexible, customized production capabilities that help medical device manufacturers and life science companies bring innovative solutions to market. SanaVita is backed by the technological expertise of its partner company, Secant Group, which is known for its transformative, next-generation biomaterials, structures, and textile designs.

Following the technology transfer, Secant Group reverse-engineered the spinal tether implant, developing numerous iterations while adhering to strict specifications (e.g. thickness, stiffness, flexibility, and durability). Upon client approval, SanaVita ensured specification conformance for device finishing, sterile barrier packaging, unique device identification, label generation and printing, final product testing, sales unit carton assembly, and sterilization management.

Result

The client submitted the finished medical device for clinical evaluation three months ahead of schedule, which gave the client extra time to prepare for market launch and assess production volume needs. The client's partnership with SanaVita continued throughout the commercialization phase of the product.



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