

TyRx Says Combination Products Offer Greater Opportunity than Drug Delivery

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TyRx Pharma, Inc. says it believes the realm of combination products holds greater financial rewards and faster access to market for its technology than drug delivery products.

On Jan. 9, the firm announced FDA's designation of its anaesthetic coated surgical mesh as a combination product with a device primary mode of action.

The company was pleased that the Office of Combination Products assign its product to CDRH because it "has historically indicated a faster regulatory and commercial timeline" than the drug center.

TyRx plans to start clinical trials by July for the mesh, which is intended to help relieve pain associated with hernia repair implants.

According to TyRx, there are about 600,000 hernia repair devices implanted each year. The New Jersey company is now building distribution channels to launch a line of hernia repair products in 2006.

The company's recent venture into combination products is a significant shift from the company's original business model. When TyRx was founded in 1998, it sought to pursue drug delivery possibilities for its proprietary bioresorbable polymers.

Although the firm has yet to market a product, its original business model entailed working with pharmaceutical companies to reformulate their drugs as proprietary agents to create new market value.

After surveying the business landscape, the company decided in 2004 to move in a different direction. According to CEO Bill Edelman, drug delivery firms "are viewed more as a commodity by pharma than as true innovators in the delivery of agents."

After five months of deliberation, TyRx decided its best opportunity to create "understandable value in the minds of potential partners" was to apply its technology to the emerging combination products sector.

The company said it was partially persuaded by a licensing agreement it has had since 2002 with Boston Scientific to co-develop novel drug-eluting coatings for cardiovascular stents. Boston Scientific made an equity investment in TyRx in January 2005.