



Cogmedix, Inc.  
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## **Success Story:** FDA-Compliant Medical Device Manufacturing of Myomo Myoelectric Upper Limb Orthosis

Myomo is one of Cogmedix's earliest and most influential clients. The relationship began when Myomo approached Columbia Tech, another wholly-owned subsidiary of Coghlin Companies, to produce subassemblies. Eventually, Myomo expressed a desire for Coghlin Companies to integrate these subassemblies into the finished medical devices, which catalyzed the relationship with Coghlin's FDA-compliant, turnkey medical device manufacturing subsidiary, Cogmedix.

Since then, Cogmedix has proven to be a reliable manufacturing resource by helping Myomo prototype and manufacture complete, FDA-compliant devices. Cogmedix was by Myomo's side as the orthoses developer's product and market focus evolved. Myomo's E100 model, cleared by the FDA as a Class II medical device, was crowned as one of *Popular Science's* "Best of What's New" personal health products of 2007. In 2012, Myomo launched the mPower 1000 and the MyoPro, a custom-fit orthosis that facilitates functional tasks and patient independence.

Along the way, Cogmedix has provided flexible, turnkey medical device manufacturing services combined with PCBA manufacturing from Columbia Tech. Cogmedix has become a supportive manufacturing collaborator with a core competency in managing varying demand cycles and product life cycles. This dedication stems from the belief that Myomo's medical technology offers an innovative solution that can greatly improve patients' lives, which is one of the core founding principles of the company.



**myomo**<sup>®</sup>  
my own motion

*"Myomo's mission is to enable individuals to overcome their paralysis by providing innovative, myoelectric orthotics and support services... resulting in an improved quality of life and lower healthcare costs."*

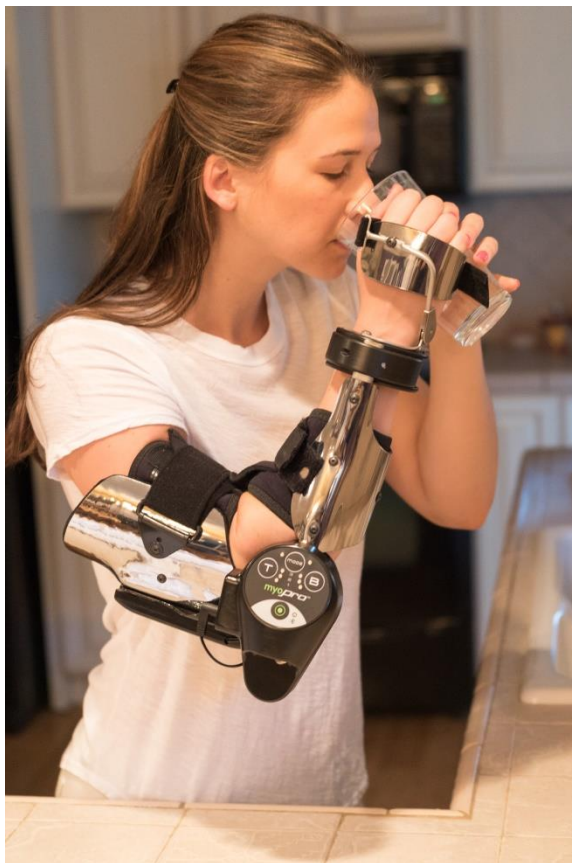
[For more information, click to visit the Myomo, Inc. website](#)

## **Challenge:** A Revolutionary Idea Streamlined for Fast, Cost-Effective Manufacturing

MIT spinout, Myomo, Inc., needed a collaborative, turnkey medical device manufacturing service provider with a priority focus on FDA compliance to help evolve its product line of upper limb orthoses.

Myomo helps people with a range of diagnoses—including battlefield traumas, workplace injuries, strokes, and progressive conditions such as ALS—to regain the use of their arms and hands. Their myoelectric braces are used to restore limb movement and function for those who have been paralyzed. Although the engineers at MIT had developed and produced the early, working prototypes of the device, they needed professional guidance to bring a product to market that could be manufactured in a repeatable and scalable manner.

By working closely with Myomo's engineers, the experienced Caring Associates at Cogmedix were able to provide design for manufacturability (DFM) feedback and collaborate on a functional version of the orthosis that would be expedient and cost-effective to produce.



## **Solution:** Flexible Services and Guidance from an Experienced Medical Device Manufacturing Team

Myomo, based in Massachusetts, was excited to work with Cogmedix in part due to their Worcester location. Their close proximity made it easy for the two teams to collaborate on the release of new products. Myomo was confident in the medical device manufacturer's ability to maintain and adhere to FDA standards and produce reliable products. More than anything, Myomo was attracted to Cogmedix's flexibility, referability, and its enthusiastic approach to collaboration. Working with the Cogmedix Caring Associates became a productive and enjoyable experience for the Myomo team.

The myoelectric upper limb orthosis has gone through many evolutions throughout the course of its product life cycle, including the acquisition and support of new market segments. Cogmedix remained flexible and adaptive by maintaining consistent communication and product quality throughout the various incarnations of the device.

## **Implementation:** Diverse Capabilities Enable Cogmedix and Coghlin Companies to Build Manufacturing Relationships That Work

As the originator of the product, Myomo had to rely on Cogmedix's FDA compliance expertise. As with any medical device, Myomo's myoelectric upper limb orthosis went through the new product introduction process, which includes process qualification, to ensure Cogmedix could meet the assembly, test and packaging requirements after their associates completed the proper competency-based training program.

Myomo came to Cogmedix with a working design for a medical device that could significantly improve the lives of its patients. Their team was keen on maintaining a rigorous pace of innovation and marketing, but lacked the manufacturing experience and resources necessary to scale their product. Cogmedix provided turnkey medical device manufacturing services, flexibility, and close proximity to the client, which enabled Myomo to rapidly apply new product enhancements, build inventory, and then refocus on other business priorities such as research and reimbursement.

The Caring Associates at Cogmedix are focused on helping clients bring their innovative designs to market ahead of the competition. Cogmedix' FDA-compliant medical device manufacturing services are supportive and flexible, allowing them to nurture and stimulate success for burgeoning innovators like Myomo, and continue to contribute to the growth of the medical device community as a whole.

### ***About Cogmedix***

*Cogmedix is a team of talented and caring associates bringing OEM medical technology to life. Providing turnkey manufacturing services to a broad range of medical and dental OEM's, Cogmedix delivers high quality products to market with compliance, competence, and commitment. Cogmedix provides a high level of flexibility in product launch and demand management, and aligns itself with innovative companies that maintain similar high standards in honesty and integrity. Cogmedix is a subsidiary of Coghlin Companies, Inc., a privately held concept to commercialization firm spanning four generations. Visit [Cogmedix.com](http://Cogmedix.com) to sign up for the e-Newsletter.*



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