



CASE STUDY

Zephyr Sleep Technologies

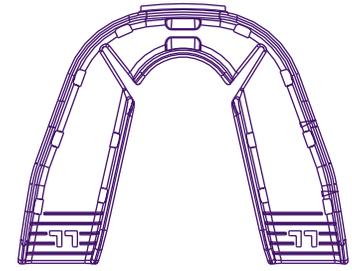


Zephyr Sleep Technologies seeks medical device manufacturing expertise; Gains design & development partner

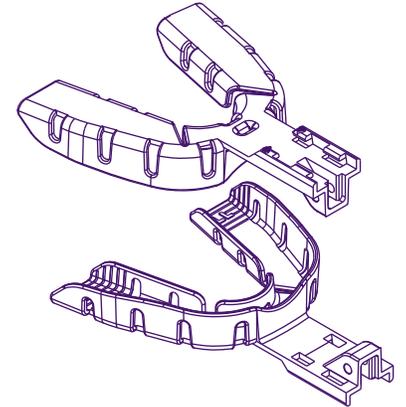


The Challenge

Zephyr Sleep Technologies is a privately-held medical device company that designs and develops products to monitor and analyze sleep performance and treat certain sleep disorders. Its MATRx™ medical device determines whether oral appliance therapy (OAT) will treat mild, moderate or severe Obstructive Sleep Apnea (OSA); and what the target protrusion is for the OAT mouthguard.



Developed by Zephyr, and based on proprietary and patented technology invented at the University of Calgary by Zephyr's Chief Medical Officer Dr. John Remmers, the MATRx™ is a medical device originally designed and produced by local Calgary companies on contract with Zephyr.



When rules in the US changed, their original Calgary contract manufacturer was no longer qualified to ship medical devices into Zephyr's target markets. Zephyr's needs also became more specific and demanding and they found that local Engineering design consultants could no longer serve their requirements. Zephyr conducted a thorough search and turned to StarFish Medical to take them to a new level, beginning with all MATRx production. In the next section, Scott and Paul tell the story.

Proven Process

"We had a great device, but needed a manufacturer knowledgeable on the specific regulatory requirements unique to the medical device industry." Further, "We needed a partner who could meet the demands of a growing company". We like the sense of partnership and trust when working with the Starfish team. Both teams are committed to delivering a quality product on a reasonable timeline. The teams share a similar cultural point of view. Expertise, respect, good fit, and free flow of information and communication are all important to any thriving relationship."

Paul Cataford
CEO Zephyr Sleep Technologies

"We engaged with Zephyr's staff to determine their immediate market and regulatory needs, and how we can fill the gaps to achieve them. In the case of the MATRx, we conducted a full audit of their DMR, production processes, and inventory, then found the most efficient means to enable volume shipment of their product from our ISO-13485-compliant factory. "

Scott Phillips
StarFish Medical President

Results

MATRx is now being installed at sleep clinics and labs all over the USA. MATRx is the first and only medical device clinically-proven to test the efficacy of oral appliance therapy as a means to treat mild, moderate or severe OSA.

Thanks to good organization on both sides and a strong team-oriented approach, Zephyr and Companies™ typical 4-6 month transfer process to less than 8 weeks from project initiation to shipment. The MATRx™ oral appliance became the fastest manufacturing transfer in StarFish Medical history. StarFish Medical now assembles and ships MATRx™ medical devices to the USA, and soon to Canada and the EU.



Bottomline

“After meeting the StarFish Medical team, we realised they were more than a typical contract manufacturing operation. When we encountered difficulties achieving electromagnetic compliance to IEC-60601 with our next generation circuit, Trevor Moat and his team took on the challenge and fixed it. As a result, Zephyr Sleep Technologies is able to move forward with next generation designs and we’re engaging StarFish Medical on additional product development changes.”

Paul Cataford
CEO Zephyr Sleep Technologies

Empowering Medtech Innovation™



Visit starfishmedical.com/tools for more medical device commercialization tools.

MATRx™ is the trademark of Zephyr Sleep Technologies.

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StarFish Medical provides award-winning design, development, and flexible manufacturing outsourcing services —100% dedicated to the medical device and life science marketplace.

StarFish partners with innovative companies to create and manufacture breakthrough products for a full range of medical specialty areas including: Cardiovascular, Digital Health, IVD, Ophthalmology, Optics, and Ultrasound. StarFish expertise includes electronics, mechanical, human factors and software systems engineering.

Our proprietary Pathfinder™ process for medical device product definition saves clients time and resources throughout the technology and product development phases to commercializa-

tion. Prototype and low volume complex electro-mechanical production are delivered in an ISO 13485 certified facility with FDA registration, including cleanroom capabilities.