



CASE STUDY:

LumiThera™

FROM PROTOTYPE TO APPROVED OPHTHALMIC MEDICAL DEVICE

Empowering Medtech Innovation™


StarFish
MEDICAL



LumiThera, Inc. was created in 2013 to develop and commercialize an early treatment for ocular damage or disease using Photobiomodulation (PBM). Two of the founders were doctors, two were engineers, and the fifth founder was company President and CEO, Clark E. Tedford, a Ph.D. in neuropharmacology.

"This is the fourth startup company I have been associated with. Starting from scratch and building a company and the team takes a lot of time and effort and includes outside groups that partner to help you, especially when you are really small and virtual in the beginning."

During the initial concept build, LumiThera engaged a design house to augment their engineers and create the "shell" around their light delivery system concept.



"As we moved forward, we recognized that our design house didn't have the later-stage development quality and manufacturing capabilities required for a medical device. We needed to find a partner who could take us to the next stage of commercialization. StarFish Medical could put the final touches around the instrument and create a manufacturing piece as well."

> Clark E. Tedford
President and CEO,
LumiThera

"We brought StarFish a device that was prototyped and had gone through some of the early clinical data. It still needed additional work to get it to the point of a commercial instrument."

WHY STARFISH?

"We needed a group that had quality systems in place that we could piggyback on. StarFish had of all the systems that could help us go from a clinical unit to a manufacturing unit and supply chain. They could still make tweaks to the instrument, and improvements both to the design and the final manufacturing unit. We didn't come with a blank slate. We actually came with a fairly sophisticated device, but it still required a lot of time and effort."

PROCESS

StarFish identified technical risks associated with manufacturing the design "as is," addressed unknown issues that are typical of all new products, and ensured the product was developed, documented and built in a 13485 certified QMS system and FDA registered facility.

While working on the transfer, StarFish completed the specification documentation and assisted with regulatory submissions (BSI for CE Mark).

- Refined and detailed product requirements and specifications to support commercial requirements
- Worked with LumiThera engineering to resolve technical issues as they arose
- Developed production documentation
- Resolved pre-production technical issues
- Conducted verification testing
- Implemented and finalized traceable development and production documentation via ISO 13485 certified QMS system. Successfully supported regulatory submissions and audits

Photobiomodulation

Photobiomodulation (PBM) involves the use of visible or near infrared light (NIR) produced by a laser or a non-coherent light source applied to the tissue of the body to provide beneficial effects in a wide range of disease states.

Photobiomodulation (PBM) stimulates cellular processes through photo acceptors and has evolved as a mainstream therapeutic modality. It is widely used in physiotherapy, chiropractic and sports medicine, and increasingly, recognized as a potential therapy for the treatment of severe and life-threatening disease states.

"LumiThera is a driven, market-focused team addressing Age-related Macular Degeneration (AMD) - a terrible, debilitating disease. It's great to help them deliver their product to market."

> **John Walmsley**
COO, StarFish Medical

RESULTS

- Commercial units are now ready for sales
- CE Mark acquired
- A path forward defined for Health Canada and FDA

LumiThera is in the process of seeking regulatory approvals and globally expanding the treatment around the world.

"We're starting to look at additional studies that will support regulatory clearance in the U.S., Canada and other countries globally."

"We're in the medical science area because we believe getting up and going to work every day, and creating something that benefits somebody who's suffering is a great place to be. At the end of the day, there is hope that LumiThera will bring something that can be safe and effective and reduce the burden of their disease."

The Valeda™ Light Delivery System ophthalmologic instrument station provides a multi-wavelength approach to treating ocular disease.

Working research and clinical units have been built to support ongoing research and development activities.

Commercial units are being designed based on the product development activities.

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"StarFish has been instrumental in building the Valeda™ Light Delivery System. We won some nice awards from manufacturing and medical device, as well as investor shows and recognition in our own ophthalmology area."

> **Clark E. Tedford**
*President and CEO,
LumiThera*



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