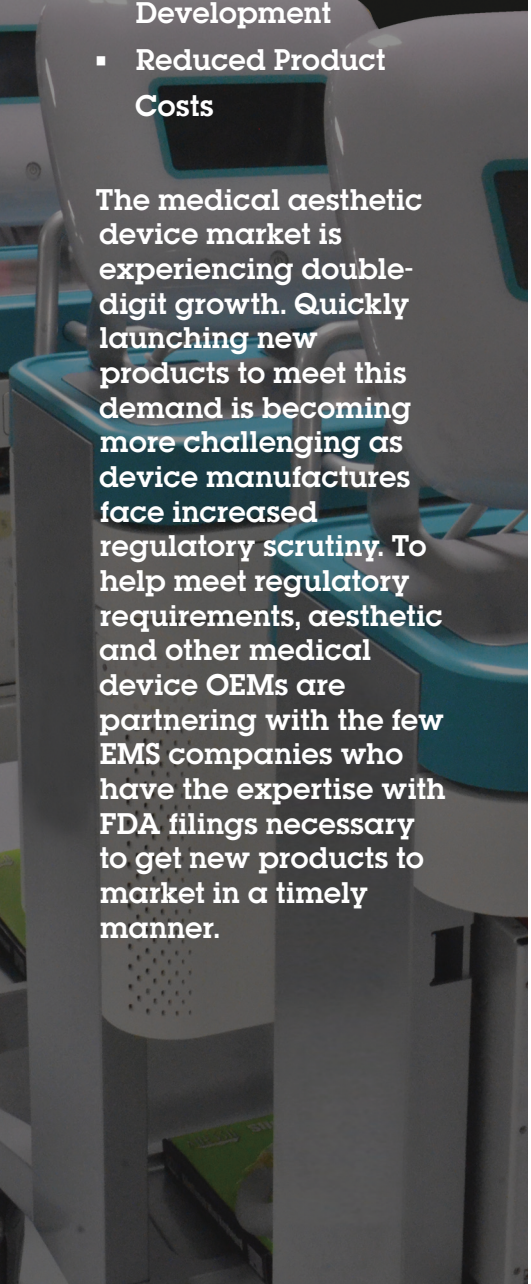
CASE STUDY

REGULATORY EXPERTISE ACCELERATES TIME TO MARKET

THE RESULTS

- Achieved Aggressive Launch Goals
- Supported Regulatory Documentation Development
- Reduced Product Costs



The medical aesthetic device market is experiencing double-digit growth. Quickly launching new products to meet this demand is becoming more challenging as device manufactures face increased regulatory scrutiny. To help meet regulatory requirements, aesthetic and other medical device OEMs are partnering with the few EMS companies who have the expertise with FDA filings necessary to get new products to market in a timely manner.

THE CHALLENGE

A global leader in skin rejuvenation and aesthetic products had developed a new laser based treatment product but did not have the resources to develop all of the documentation necessary to support regulatory and FDA approval. In order to get the product to market, the company realized they needed to engage with a global EMS partner with facilities certified for medical device manufacturing and the regulatory expertise to support the successful launch of their product. They chose Sanmina.

THE SOLUTION

Sanmina's Medical Division includes a team of regulatory compliance personnel able to provide medical regulatory services to customers. These services helped this customer bring their product to market more quickly.

- **Onsite Engineering and Regulatory Staff**
  Sanmina assigned a team of engineers together with a regulatory compliance officer and placed them onsite at the company to work with their designers and help prepare the required documents, including the DMR. By having a team onsite early in the design and production cycle, Sanmina was able to provide feedback, optimizing the design for manufacturing and, ensuring the product was released on time.

- **Prior Experience/Supply Chain Leverage**
  Sanmina manufacturers a wide range of medical products and had prior experience producing aesthetic rejuvenation products, including critical experience with laser and high intensity light technology.

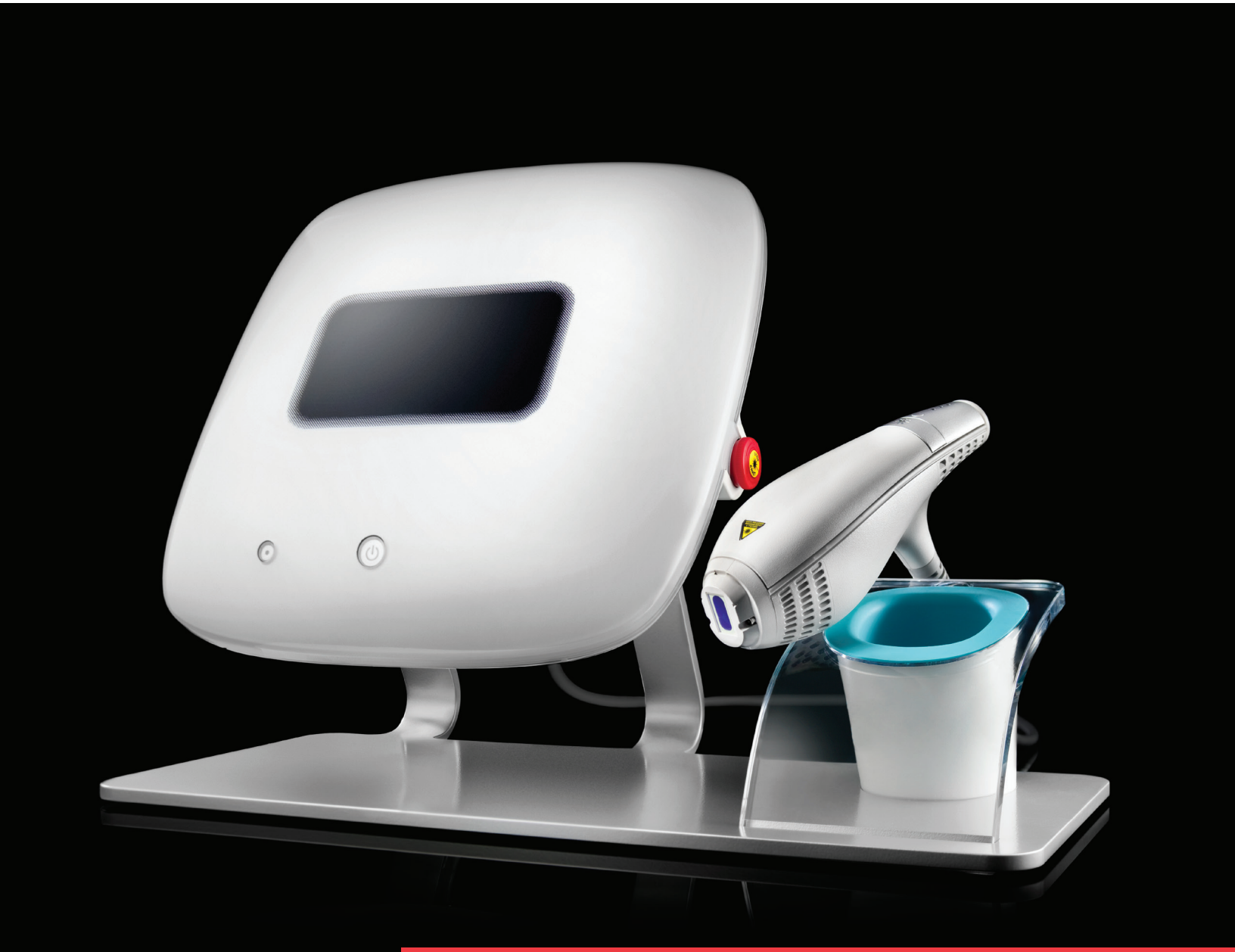
- **Regulatory Documentation Control**
  Early engagement in design and product engineering was supported by Sanmina's proven and Part 11 compliant documentation control systems. Sanmina's documentation system provides revision control and a secure repository for all product documentation, manufacturing instructions and processes. These systems are consistently deployed in Sanmina's medical facilities all over the world.

- **ISO 13485-2003 Certified Facilities**
  Sanmina has more FDA and ISO-certified facilities than any other medical EMS company in the world. Sanmina has 21 ISO 13485-2003 Certified facilities including 9 FDA registered facilities.

- **Robust Manufacturing Systems**
  Sanmina has robust systems in place for medical product manufacturing, refined over a period of more than 20 years. Sanmina's production systems and software are also FDA Part-11 compliant.

MOVING FORWARD

After working side by side with the company's engineering team, the new aesthetic rejuvenation product was successfully launched. Sanmina continues to make these products, has introduced another new product for this customer, and is in the early stages of product design and development for their next generation device.



ABOUT SANMINA

Sanmina makes some of the most complex and innovative optical, electronic and mechanical products in the world. Recognized as a technology leader, Sanmina provides end-to-end design, manufacturing and logistics solutions, delivering superior quality and support to Original Equipment Manufacturers (OEMs) primarily in the communications networks, computing and storage, medical, defense and aerospace, industrial and semiconductor, multimedia, automotive and clean technology sectors.

More information regarding the company is available at http://www.sanmina.com.

CS01_ST_020614