# Case History 39
## Solea Dental Laser
## Convergent Dental


**Market**

Dental

**Client Type**

A startup company, Convergent Dental, is bringing the Solea laser a revolutionary dental device to market.

**Unmet Need**

The Solea laser reduces the pain due to hard and soft tissue ablation and eliminates the pain and anxiety of dental procedures.

**Approach**

Convergent Dental's $CO_2$ laser system enables the dentist to deliver fast, precise, virtually noiseless and anesthesia-free for the vast majority of hard and soft tissue ablation procedures.

**Product Features**

The product utilizes a 9.3 micron wavelength $CO_2$ laser to painlessly ablate hard and soft dental tissue.

**Services Provided by OTI**

- Engineering
  - Developed friction lock for articulating arm
  - Documentation and drafting of components and assemblies
- Transition to manufacturing
  - Determination of subassembly fabrication
  - Assembly procedures were developed
  - Test procedures were reviewed
  - Manufacturing personnel at Cogmedix were trained on prototype build
  - Supply chain and bills of material were developed in partnership with Convergent engineering and Cogmedix
  - Manufacturing support at Cogmedix for pilot assembly
- Benefits
  - Cost effective and timely development of manufacturing procedures
  - Development of supply chain to ensure rapid transition from prototype to pilot build
  - Smooth transition from prototype to pilot build
  - Assembly cost targets were achieved

**Customer Comment**

*"As a medical device startup, the initial design transfer of our first product to a contract manufacturer was a huge task. OTI guided us through the development of manufacturing instructions, test procedures, and worked with us to improve the manufacturing transfer steps of our Design Control process. OTI's network of consulting resources also helped us implement CFR 820 compliant drawing control processes for managing our extensive CAD files and schematic library. As a result of the attention paid by the OTI project manager in properly documenting each step along the way, our preparation of the design transfer quality records for our initial FDA audit was very straightforward."*
- Jon Quillard, VP Regulatory Affairs

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