

# The Challenge: Meet FDA Requirements and Reduce Costs

## International Medical Device Manufacturer - Medical Imaging Server

### The Client

A NASDAQ listed provider of advanced image analysis and workflow solutions, this client is engaged in the development of advanced computer algorithms that verify and enhance visual diagnostics. The products are used by radiologists worldwide.

The client offers a range of computer aided cancer detection systems to healthcare practitioners through a direct sales force and through partnerships with leading medical suppliers.

### The Business Problem

The medical service provided is designated by the FDA as a "Class III" medical process. Because of its Class III classification, the computer server used for the processing of the algorithms must be certified for safety standards UL60950-I, FCC Part 15, CISPR 22, EN55024 and others. It must also meet a similar list of standards for international locations.

The Client was looking for a supplier more responsive than their original supplier. In addition, the Client wanted to reduce the cost of the servers used for their application.

Engaging with the ConRes OEM/Embedded Solutions Group enabled the development of a solution that not only met all of the Client's technical and certification requirements, but also reduced costs by 45%.

### Client Requirements

- ▶ Proven experience building and supporting OEM servers
- ▶ UL 60950-I safety certification;
- ▶ FCC Part 15 certification
- ▶ CISPR 22 certification
- ▶ EN55024 Certification
- ▶ International Safety Standards
- ▶ Overall cost reduction
- ▶ ISO registration
- ▶ Tight design processes and change order systems

- ▶ Stocking of components to mitigate end-of-life issues.

### The Initial Solution

To meet the necessary certification requirements, the OEM/Embedded Computing Solutions Group of Continental Resources (ConRes) recommended an Intel-based system.

As an authorized Intel partner, ConRes participates in the Intel Premier Provider Partner Program. Through this program ConRes is able to build systems which carry the necessary certifications for medical computer systems without having to go through costly safety testing. This eliminated approximately \$20,000 of certification testing costs.

In addition, after reviewing the system specifications and analyzing the design and component selection, ConRes made recommendations that resulted in a reduction in the system costs of over \$1,000.

ConRes, the Client, and the Client's Class III assembler (who provides final system integration services under FDA Class III regulations) worked together to set up a custom ordering and delivery system that cut delivery time to one day. Inventories are managed in accordance with the Client's just-in-time delivery schedule and to cope with issues related to product changes in a tightly controlled medical product.

To meet the inevitable changes in minor components, ConRes works with the Client's product managers to assure timely and well-documented engineering change orders without upsetting deliveries or violating FDA product control regulations.

The success of the initial product program has led the Client to have ConRes build a second product and a range of products for a new medical service is being evaluated.

### Benefits

- ▶ Through careful design analysis and component sourcing, ConRes reduced the direct cost for the Client's medical server by over 45%.
- ▶ As an Intel Premier Partner, ConRes saved the Client approximately \$20,000 in certification fees.

- An inventory stocking plan has resulted in 100% on-time deliveries - including meeting the demand spikes that frequently occur at the end of business quarters.
- Embedding Intel's roadmap products has extended the lifespan of each server to over four years.
- By extending the lifespan of each server, the time and costs associated with changing an FDA-controlled product are minimized.

Outsourcing to ConRes enables the Client to stay focused on their core competencies of medical imaging and algorithm development.

Extensive experience and strategic vendor partnerships enables ConRes to construct medically certified, reliable servers that not only meet the Client's product and logistics specifications, but have proven to save the Client substantial costs both now and in the future.

Build a better product line, maximize your choice of OEM solutions and services, and strengthen your ROI – with Custom, OEM/Embedded Computing Solutions from Continental Resources (ConRes).



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