PHOENIX ANALYSIS & DESIGN TECHNOLOGIES

We Make Innovation Work

Project Name: ClearView
Application: Non-invasive measurement device
Customer: EPIC Research & Diagnostics
Website: http//www.epicdiagnostics.com

CLEARVIEW: A NOVEL MEDICAL MEASUREMENT DEVICE

BACKGROUND AND PROJECT CHALLENGE

Diagnostic tools play a vital role in providing good patient care and in serving the R&D efforts of our medical community. The ClearView device provides a new way to gain insight into the patient's condition in a low cost, non-invasive way. Our challenge was to help EPIC navigate the product commercialization process and take their prototype to a fully verified and validated product. As of spring, 2012, tooling has been made and pilot production was complete.

From 2010 - 2012, PADT worked with EPIC to help them develop their ClearView diagnostic technology.

PROCESS AND SOLUTION

When PADT first began to work with EPIC, the ClearView prototype had some electronic issues that were affecting its performance. The power circuit topology was incorrect and lead to poor high voltage wave forms. At the same time, there was a need to prepare devices that were suitable for clinical testing. To solve these issues, PADT redesigned the aspects of the system that were preventing successful clinical work. This included a redesign of the high voltage circuit board and firmware. A risk evaluation and safety review was then performed resulting in adjustments necessary to insure successful device production for clinical use. PADT then fabricated 4 units, conducted the appropriate acceptance testing, and delivered the units to EPIC for clinical testing at a Johns Hopkins affiliate. This early clinical work helped establish the basis for EPIC's 510(k) submission.

After delivering units for clinical work, PADT helped EPIC bring their development into alignment with ISO 13485 requirements. For this, we employed PADT's ISO13485 design control system and we worked

DISCIPLINES EMPLOYED

Electrical/firmware engineering

Mechanical engineering and industrial design

Verification testing

Limited manufacturing to support clicical trials

FDA 510(k) submission support

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with EPIC to create a development plan. Also, we worked to improve and formalized specifications with suppliers. This process also lead to a documented verification and validation plan.

After bringing the device under design control, work proceeded with rigorous evaluation and additional design improvements. The early design had several issues. First, the unit was failing housing impact tests. Therefore, the housing was redesigned for greater impact resistance and at the same time improved ergonomics. These changes required new tooling be developed for injection molding. Second, the variability found in the high voltage electrode performance was too wide. PADT redesigned the electrode assembly to improve performance, reduce variability and improve the manufacturability of the system. Finally, there was a high voltage breakdown between components on the board. The high voltage transformer was creating a corona with the adjacent capacitor in some situations. To alleviate this problem, PADT redesigned the main control circuit board for better high voltage performance and isolation. After these changes were made, PADT worked with TUV for product safety testing. Simultaneously, we conducted early verification testing to verify electrical and firmware function within the unit, including output waveform of the new high voltage transformer. All of this work supported the 510(k) submission.

Our final step in this product development was to implement production. PADT suggested several contract manufacturers (CM) from our supplier database and a CM was chosen. Then PADT worked to transfer the design to the CM for production. This effort included: assistance in the development of procedures and work instructions, training of assemblers and acceptance test personnel, selection of electrical product safety testing equipment, transfer of all fixtures PADT had developed for earlier builds, transfer of all documents (including a complete drawing package), transfer of our approved supplier list, and finally review of formats to insure compliance with ISO13485. After this effort, PADT participated in a production readiness review which included the CM and EPIC quality personnel to insure that everything was in place prior to a pilot run. Finally, work was done with TUV for first factory inspection (FFI). As of spring 2012, the pilot run of production is complete and full scale launch is scheduled for the fall of 2012.

PROJECT HIGHLIGHTS

Started with EPIC's prototype device which had performance issues

Solved the issues with the high voltage section of the device to improve performance

Developed detailed design plan and provided input to EPIC for the design history file (DHF)

Worked to improve EPIC's supply chain and to formalize component specifications

Provided four functional devices for use in clinical trials at a Johns Hopkins affiliate

Modified the device design to improve safety and ergonomics

Supported 510(k) submission

Conducted Verification testing and supported the Validation effort

Helped implement manufacturing with local contract manufacturer recommended by PADT

TESTIMONIAL

"For the last 2 years we have worked with PADT to develop our ClearView technology. Their team has helped us with many aspects of product development and commercialization. They have been a very valuable asset and I would highly recommend them to any startup that needs to navigate the pathway to market."

Tom Blondi
President

EPIC Research & Diagnostics

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