



PRODUCT DEVELOPMENT FOR Start-Up Medical Equipment Company

Challenge

A medical imaging startup in Rochester, NY, developed an innovative approach for low-dose breast and extremity 3D CT scanning. The customer commissioned PEKO to commercialize the existing prototype design for manufacturability, safety, durability, ease-of-installation, and serviceability, while improving the unit's critical performance characteristics.



Executive Summary

Industry: MEDICAL
Company Type: START-UP
Location: NEW YORK

01 | Timeframe

- 6-8 Month Development
- 2-3 Month Prototype Build

02 | Capabilities Utilizes

- All Engineering Disciplines
- Tool Room & Electricians
- Quality Management System
- Procurement
- Packaging and Logistics

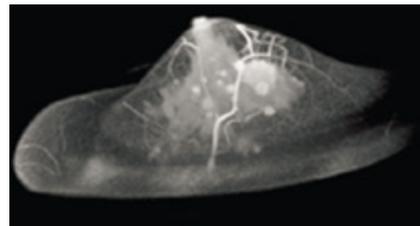
03 | Results

- ISO 13485:2016 conformance; FDA cleared
- Improved end-user interaction
- Took prototype design to first generation commercial product

Solution >>

With productivity in mind, PEKO's team incorporated design elements specifically to enhance the product's value to all stakeholders, including doctors, patients, technicians, and service/installation personnel. To increase functionality, PEKO designed and built a combined vertical and horizontal telescoping enclosure package to resolve safety and access issues allowing doctors and technicians to efficiently work with patients. PEKO also developed a customizable umbilical cable system design to increase installation site flexibility. A unique shrink-fit bearing installation technique utilizing dry ice was developed to accurately fit the main bearing to significantly improve image quality. PEKO guided the product through third-party (ETL) medical product safety testing. With the PEKO developed optimized designs, final image quality was greatly improved, resulting in more accurate and repeatable cancer cell detection.

Success >>



The product development was completed and multiple units were built utilizing PEKO's ISO 13485:2016 certified manufacturing capabilities. The units were placed

into clinical trials at medical centers nationwide. The product has been FDA cleared and successfully improves the cancer screening process for patients.