PRODUCT DEVELOPMENT for
Start-Up Medical Equipment Company

EXECUTIVE SUMMARY

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

Timeframe:

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

Capabilities Utilizes:

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

Results:

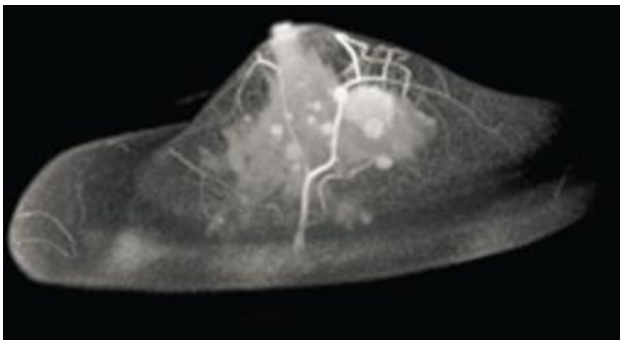
- ISO 13485 compliant and FDA cleared
- Improved end-users interaction
- Took prototype design to first generation commercial product

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.

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 compliant 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.