APTYX

CASE STUDY

Startup leverages molding & complex assembly to deliver novel embolic catheter

Catheter delivered for 510(k) submission in only 6 months

Customer Situation

A precommercial startup serving the interventional radiology market was facing a tight timeline to develop a complex microcatheter designed to deliver a novel embolic device. The customer needed product to continue its clinical trial and meet the timeline for its critical regulatory deadline.

The customer was looking for a new partner because its supplier was no longer producing the device. They chose to work with Aptyx because of its experience with complex catheters, molding expertise, and in-house secondary operations for catheter assembly.

Solution

The Aptyx team worked closely with the customer's team to accelerate the timeline, working jointly at Aptyx's facility and collaborating to develop protocols and reports.

The complex, delicate device featured a very long (6') shaft with an OD of less than .5 mm that had to be perfectly straight in the tool. The team leveraged expertise and resources from across the company to develop and implement key processes, including overmolding, complex catheter assembly, leak and flow testing, and laser engraving. Team members expedited the tooling process to deliver parts to meet their needs within their tight timeline.

After meeting the critical regulatory deadline, the Aptyx team is now applying design for manufacturability (DFM) principles to examine the manufacturing process and ensure that the device can be manufactured at scale.

Results

Collaborating closely with the customer, the Aptyx team successfully manufactured and assembled the complex microcatheter in an expedited time frame to meet an aggressive regulatory 510(k) submission deadline of only 6 months, which enabled the company to continue its quest to deliver a novel therapy to patients.

The team continues to partner with this customer, working through ongoing DFM optimization on the path to commercialization.

Met regulatory 510(k) submission deadline of only 6 months