Boulder BioMed
Family of Companies

Boulder BioMed Secures FDA Clearance, Market Launch for Embolization, Inc.

Integrated family of services takes multi-year struggle to successful product launch

Boulder BioMed is a vertically integrated medical device development company. The family of expert contract consulting businesses provides life sciences companies all the resources they need to bring products to market, from napkin sketch through sterilization validation and packaging. Along the way, the company offers engineering, manufacturing, sterilization and packaging, distribution and packaging services, and regulatory affairs consulting as well as implements quality management systems.

Wherever any business unit of Boulder BioMed enters the process, with any services, the goal is focused and consistent: to help speed products to market. Embolization, Inc., is a prime success story of how Boulder BioMed took a product from being unable to make it to market to consistent manufacturing and market release. Where the client struggled without success for years, Boulder BioMed succeeded.

Novel technology from Embolization, Inc.

With expertise in radiopaque, shape-memory, biocompatible polymers, Embolization specializes in developing minimally invasive medical devices for peripheral vascular and neurovascular uses in the interventional radiology market.

The company's NED device is a novel, radiopaque, polymer-based embolic coil. Using proprietary shape-memory biocompatible polymers, NED improves vascular occlusion while minimizing artifacts in CT and MRI imaging that occur with traditional metal devices.

Evolving the relationship from a single service to full operational support

Yet the original version of the product was unable to obtain 510(k) clearance due to biocompatibility testing issues. Introduced to Boulder BioMed's Boulder Sterilization business to sterilize the product, Embolization, Inc., quickly realized that the company had much more to offer – more in the way of expertise and experience that could help them address a host of prior issues and get their product on the market.

So while work began with sterilization services, the relationship evolved into a more comprehensive consulting contract through which Boulder BioMed delved into design, regulatory, manufacturing and other processes. Embolization eventually contracted with Boulder BioMed to take over all over all of their operations, including the employ of Boulder BioMed's principal as fractional CEO.

FDA clearance, market launch

Along with recapitalizing Embolization, Boulder BioMed's experts were able to identify and address three main challenges that had prevented the company from obtaining critical 510(k) clearance:

- Biocompatibility
- Manufacturing difficulties
- Balance of radiopacity with strength of the polymer

Passing biocompatibility testing was a major hurdle for the novel polymer. Boulder BioMed developed a proprietary processing method to render the polymer biocompatible, conducting extensive animal testing as well as extractables and leachables testing.

The work was successful. Embolization obtained 501(k) market clearance in 2025. Where Embolization had struggled for years, Boulder BioMed solved the problems and achieved the FDA clearance goal effectively and efficiently.

The Boulder iQ business unit of Boulder BioMed began to manufacture the devices soon after Embolization received FDA clearance.

Today

NED is in limited-market release, with use cases topping 70 coils across four institutions and physicians. Users say the device is effective, occluding vessels quickly and effectively, with much better pack density than other coils on the market. One physician has deemed NED the "next generation" in embolic coils.

Boulder iQ, the arm of Boulder BioMed that moves products from concept through manufacturing, continues to manufacture the devices in its Class 7 clean room.

Conclusion

The Embolization case illustrates the effectiveness and success of Boulder BioMed's integrated program of services. Far more than just manufacturing and assembly, Boulder BioMed brought together and integrated the experts, the experience and the skills to identify the problem, develop solutions and deliver an effective device to the market. The ability to secure services as needed, under one umbrella, demonstrated success.

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