

Precision Microdrives Motor Case Study

Surgically Implanted Medical Equipment, USA

THE CHALLENGE

The medical industry is subject to stringent oversight, and requires approvals from multiple medical and governing bodies. Any deviation from a product specification, is a costly and time-consuming exercise.

Our customer received an end-of-life notification at the end of a string of negative experiences with their existing Asian motor manufacturer. Consequently, our customer desired a Western partner to manage the complexities of manufacturing a brushless vibration motor, within a Food and Drugs Administration (FDA) Class III medical implant device. They required us to maintain full compliance, strict quality standards, and provide detailed technical 'after-sales' support.

They had 2 years worth of last-chance-to-buy stock on hand before production-stop, and shared the specification with us in the hope that we could provide a solution. We had to minimise the impact of complex resubmissions to the FDA.

THE SOLUTION

Due to the nature of the product, an off the shelf solution, was not possible. Instead, we examined the options, and proposed a modified version of an existing motor design. Modifications were limited to a few core sub-components, resulting in a simpler and faster resubmission to the FDA, to get product re-approval without stopping the production line.

Communicating accountability of product quality, and traceability of components, was of vital importance to our customer. Our experience, know-how and local SE Asia infrastructure enabled us to bridge language, cultural and process gaps. This supported us to deliver extensive audit documentation of our upstream manufacturing plant, undertake in-depth quality checks, and perform lifetime reliability testing and product validation.

THE RESULTS

- Our expertise and approach to technical design, prototype and manufacture, simplified the FDA re-approval process and limited associated costs.
- The new motor is more reliable due to it containing 3 driving coils compared to 2, which was utilised in the previous motor design. Our industry-leading testing, validation and quality control systems enabled our customer to quickly identify the new product, as being superior and more reliable to the previous one.
- With original motor stock running low, we delivered a solution in time, that avoided a costly redesign of the product, and avoided any production down-time.

OUR RELATIONSHIP

We quickly became a strong and reliable partner throughout the design and manufacturing process, mainly because we addressed their problems directly, and managed their risk throughout the whole project. In this way we proactively built a lasting trust between ourselves and our customer.

