BUILDING AND MANAGING THE SOFTWARE FOR A CLASS III MEDICAL DEVICE:

From concept to FDA approval to current version controls

Voler SYSTEMS

Our client is developing an FDA-approved Class III medical device, a percutaneous heart pump, that is deployed during heart surgery procedures. As a medical device company, the client was focused on mechanical engineering, and sought a software development partner to help build the application and firmware, and perform verification testing.

RESULTS

- ✔ Zero revision request, first-time right approval from FDA on software
- ✔ Continuous code improvement for latest product versions
- ✔ Collaborative project management, where client owns the requirements and we own the delivery cycle

OVERVIEW

Our client is a leading medical device design and manufacturing organization that developed a percutaneous heart pump (PHP) as a hemodynamic support system during high-risk coronary interventions. The device is able to move up to five liters of blood per minute. It is inserted percutaneously via the femoral artery using a 14 French sheath and, once delivered into the aortic valve, expands to 24 French, eventually delivering near-normal blood flow through the vessel.

The PHP was designed to impart low shear stress to the blood flowing through the pump, helping to reduce damage to blood cells, the chance of clot formation, and the potential for a stroke.

As a Class III medical device, the company has to go through a stringent FDA approval process, and every element associated with the device, from clinical trial data to the actual software running the product, are reviewed in depth.

VOLER AS THE SOFTWARE PARTNER

Voler was introduced to the client as a referral from a prior project with another client, and we were required to write the firmware and software for the product and perform the verification protocol. As the client was focused on the device mechanics, we became the ideal software partner.

Our participation extended to the following areas:

- The software for the controller creates more than 100 error messages to report user errors and device malfunction. We had to check every combination for every error message to make sure it was reliable and working in all conditions.
- The company that developed the electronics is no longer in business, so we reviewed and fixed a number of problems in the electronics.
- The PHP has a controller device to control pump speed and monitor blood flow, and as a Class III device, it runs on both batteries and AC power to provide uninterrupted service. The client discovered that the battery would not charge after one year of storage. We performed tests to identify the problem, recommended electronic changes, and modified the firmware to ensure it would charge correctly.
- As a Class III medical device, the FDA inspection is intense and wide-ranging. The FDA is more concerned about software than any other part of a medical device. We wrote the verification protocol, executed it, and created documentation that was submitted to FDA for approval. The FDA approved the software without any questions—almost a first. A few months later, we wrote some revisions to the software, again ran the verification, and it was submitted to FDA. Again it was approved with no questions.
- During compliance testing, it was discovered that the electro-static discharge testing failed as the grounding near the display screen was inadequate. We worked with our client to undertake the complex scope of figuring out the failure area, and we recommended design changes that fixed the problem. As the screen could not be covered in metal, we had to design a special metal backing and grounding that solved the problem.
- Since this was a new engagement for this medical device company to develop software, we enabled a smooth project plan—where we helped the client organize requirements using our guidelines and set expectations as to what the software is required to do. Our project management of the software has blended with the overall project management by the client to provide high quality results.

OUTCOMES

- Voler has been a partner of choice for the client during the long product design process.
- Voler has played a key role in the client's FDA approval program.
- Voler continues to be an integral partner in the client's product design.

> *We have been through multiple acquisitions, and our reliable partner through all the changes has been Voler. If we were asked to replace Voler as a vendor, it would be a non-starter.*
>
> *Client Principal Engineer*