D&K's early engagement with UL gets Bioness' Vector Elite on the market on time

Background

Bioness, a U.S.-based medical device company, is focused on developing products to help individuals around the world with neurological impairments regain their independence. The company contracted with D&K Engineering, a 14-year-old global product realization company, to develop and manufacture the Vector Elite, a body weight support system designed to accelerate physical rehabilitation of patients with severe gait or balance impairment.

Unique Challenges

The Vector Elite is a complex system with many components. At a high level, the device enables a patient to walk along a predefined path while a winch unloads a precisely controlled amount of the patient's weight. An active trolley that contains the winch and various electronics components follows the patient.

To perform its functions, the device architecture includes computers as well as electrical and mechanical components, classifying the device as a programmable electro-mechanical system (PEMS in FDA parlance). PEMS devices inherently have many risks and multiple safety-related requirements that must be met to address potential risks for both patients and users. By taking on this design project, the D&K Engineering team was faced with the challenge of meeting these complex safety requirements.

First, the Vector Elite product is a first-of-its-kind, highly computerized electro-mechanical system for use in patient rehabilitation. This product's unique challenge is the power rail system used to run the device and the use of wireless communication to control it via a handheld remote control. Due to the innovative nature of the product, the typical design elements detailed in the safety standards had to be assessed for risk.

Second, although there are core components, the overall medical system is intended to be permanently installed in custom configurations. This led to challenges in determining what representative samples/configurations were required for testing.

Third, not only did the device need to be compliant, but so did the manufacturing factory. A factory audit was required for compliance to determine that all appropriate manufacturing processes were in place and met requirements.

Finally, Bioness' business need dictated an extremely aggressive certification schedule to meet global regulatory requirements – beginning in the US and Europe – and to fulfill sales obligations and business goals.

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-Moshe Olim
Senior Systems Engineer,
D&K engineering

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The Solution

To address these challenges, D&K Engineering began by reaching out to the local UL account executive. Together, they came up with a plan to meet the aggressive schedule and global product launch objectives. D&K chose UL primarily based on UL's brand recognition by Bioness' customers. With UL recognized worldwide as the authority in safety science, Bioness' customers are familiar with the brand. Because UL has local offices near the D&K Engineering facilities, UL representatives were able to interact in real-time with an experienced engineer, who was located close enough to work face-to-face, as needed. D&K involved UL very early in the design process, before making significant design decisions. This enabled D&K to ensure it was designing to the correct standard and eliminated any ambiguities in interpretation of the standard.

D&K also prepared the appropriate documentation and had UL review it prior to having the hardware ready to test. This pre-certification review reduced the overall time to complete the certification process.

Finally, close interaction with UL helped ensure the hardware testing was being done properly to meet the standard's requirements.

"Although we have assessed hundreds of devices to IEC 60601 standards, each device and company are unique," said Mitch McGarry, UL staff engineer at UL's Brea office. "It was very helpful to review the product early in the design in order to help the D&K team with compliance and avoid any rework/mistakes that could have cost valuable time. Once we had our initial meeting, we were able to create a schedule so that UL's assessments could be integrated into their design process. This allowed for UL engineering services to be delivered at specific milestones specified by D&K. We could then track the progress of the overall certification and identify any areas that needed additional resources to ensure a successful and timely project completion. "

Outcome

The Vector Elite system design was declared 60601-1 (3rd edition) compliant and the manufacturing on the device was also UL certified with the aggressive project time schedule allowing Bioness to gain significant market advantage.

"The IEC 60601 3rd edition is a very complex series of standards, and even the most experienced medical device manufacturers have had challenges complying on the first certification submission," said Brian Weller, director of quality at D&K Engineering. "The fact that D&K Engineering completed submission on schedule and budget is a result of approaching this project in a collaborative manner."

"Having the process start very early allowed us to benefit from UL guidance and sharpened our focus on the right items to ensure UL compliance," said Moshe Olim, senior systems engineer at D&K Engineering.

"The way D&K and UL worked together is an excellent example of how to approach certification," said Mitch McGarry. "It was really rewarding to be able to work together early in the design process, offering feedback. By making the personal connections during the early stages, D&K engineers were able to contact me directly when they had questions or needed additional engineering support. We were working together as one team."