JACE Systems
Foreign Compliance Case Study (May 2017)

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BACKGROUND

JACE Systems designs and manufactures continuous passive motion equipment (CPM) used by patients recovering from orthopedic surgery for rehabilitation. It was founded in 1989 and has 12 employees. International represents 12% percent of sales.

EUROPEAN MARKET

In the US, JACE's equipment is categorized as a low risk, Class I medical device. Although the company is an FDA licensed medical device manufacturer with 510K clearance, its Class I products do not require an FDA audit. However, as JACE explains, in Europe its product is a higher risk Class 2A, because it has an electric motor − even though "our product is basically exercise equipment."

JACE got its first CE Mark in 2009. CE Mark is used in the EU to indicate compliance with all applicable directives and is necessary to sell medical devices in the EU.

When a CE Mark became necessary, several requirements needed to be addressed, such as electrical safety, safety in case of fire (smoke), EMI interference, etc. While working toward compliance, JACE's export sales were impacted. JACE worked with one outside company to achieve compliance with ISO 13485 (which specifies requirements for quality management systems related to medical devices) and ISO 9000, which are both pre-requisites for CE marking (for the EU Medical Device Directive). In addition to ISO certification, CE Mark also requires a technical file that JACE claims, "took a while to put together." It included "lots of paperwork" – labels, manuals, test results, risk management plan, product photos, etc., which resulted in 4 folders for one piece of equipment. BSI (www.bsigroup.com) was its Notified Body (organization designated to assess compliance with regulations) for its CE Mark. Eventually it got through all the testing and qualification processes. It was a lot of effort JACE says, "just to sell 70 machines to Germany since 2014."

For many medical devices, CE certification requires annual audits by a Notified Body to ensure ongoing compliance. Similarly, ISO certification is also "audited" with surveillance visits on an ongoing basis to ensure compliance. JACE is currently dealing with what it describes as a "surprise" audit from its CE auditor. JACE received similar audits from them in 2015 and 2016 as well, each time costing JACE $5,000. JACE is also currently working toward ISO certification to the current standard. The company working with JACE on ISO is also supposed to be auditing JACE to the CE standard and should be submitting this information to their CE auditor. But instead, JACE is being audited by both companies (and is thus paying both).

According to JACE there have been some changes to electrical testing requirements for EU directives, part of small changes that are incorporated on an ongoing basis. In addition, ISO standards 13485 and 9001 are significantly changing their approaches to risk management. JACE says, "It practically takes an interpreter to understand it."

The company gets its information on EU compliance primarily through self-research; auditors are not acting as consultants to JACE (as paying them to act as consultants would be an additional cost to auditing fees). JACE claims there are very good websites for information, such as https://elsmar.com/Forums/, where companies can discuss requirements with experts, some blogs, and the European Commission site for information on

documentation requirements for the Medical Device Directive (MDD). However, the company says it is not easy to self-inform.

OTHER MARKETS

Mexico, South America and Canada each have their own regulations and documentation and, according to JACE, it can be expensive to comply with each country's specific requirements. This is particularly true if you use some of the higher priced vendors such as UL or BSI. For example, it may cost $25,000 for an EMI test with these "brand name" companies versus $10,000 with lower cost compliance companies. Further, these costs are in addition to whatever product changes must be made as a result.

Japan requires conformance with ISO standards (such as 13485) and a government auditor visited the company's facility. In addition, Japan required a certificate of testing for compliance with IEC 60601-1-1 (medical electrical systems) and 60601-1-2 (electromagnetic compatibility) safety standards, which cost $30,000 from Intertek (www.intertek.com, a Nationally Recognized Testing Laboratory). IEC 60601-1 is a medical electrical equipment harmonized standard recognized by most countries.