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After a meeting with the FDA, Pavmed (NSDQ:PAVM) said that the agency wants to see more clinical testing for the CarpX device before it can make a decision on whether or not to approve the product.

In August last year, the FDA group reviewing Pavmed's 510(k) application for CarpX requested that the company resubmit the application because the group hadn't reached a consensus within the designated review period.

The hangup, according to an SEC filing, is that the group is "focused on protection of important structures during the procedure. [The FDA] recommended clinical testing to definitively document procedural safety in humans and provided initial guidance on parameters for this testing."

The FDA reportedly told Pavmed that a well-designed study outside of the U.S. would be sufficient to prove that CarpX, a minimally-invasive device designed to treat carpal tunnel syndrome, is safe.

The company also announced that it expects to submit CarpX for CE Mark clearance in the European Union by the end of this quarter.

"I am very pleased with how this week's pre-submission meeting and follow-up interactions with the FDA have gone," chairman & CEO Dr. Lishan Aklog said in prepared remarks. "The goal of the pre-submission process is to receive clear and definitive guidance on what the company needs to do to demonstrate substantial equivalence. I am grateful that the FDA personnel showed up in force, despite the government shutdown, and engaged in a substantive conversation during which we were able to secure that guidance."

The post Pavmed plans safety study for CarpX following FDA meeting appeared first on MassDevice.