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Securing FDA approval for novel OPRA prosthetic wasn't a 'slam dunk.' Here's how start-up Integrum made it through the PMA maze

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When medtech industry attorney Jonathan Kahan began working with Swedish start-up Integrum AB to secure premarket approval (PMA) from the U.S. Food and Drug Administration for the company's novel OPRA prosthetic, he wasn't sure the agency would ultimately approve the device.

"When we started this project, this was not necessarily a slam dunk," Kahan, a partner with the law firm Hogan Lovells, told *Medtech Insight*. "This actually, in my experience – and I've been doing this for about 40 years – was a very difficult project."

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