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06 Dec 2018 | **News**

QUOTED. Dec. 6, 2018. Bram Zuckerman.

by

The first US FDA device advisory panel to address a product on FDA's Breakthrough Devices program overwhelmingly supported Impulse Dynamics NV's *Optimizer Smart* system, an implant that delivers cardiac contractility modulation to patients with heart failure. The recommendation came despite panel uncertainty during a Dec. 4 meeting as to whether there was enough trial data to prove safety and effectiveness. See what Bram Zuckerman, the director of FDA's division of cardiovascular devices, said about it here.

“You may disagree with the methodology, and the sponsor may need to explain how the exchangeability worked, but a key tenet of this [Breakthrough] pathway is that sponsors can propose new methodology to show safety and effectiveness.” –Bram Zuckerman, director, FDA division of cardiovascular devices

- Find out more: *FDA Device Panel Delivers Thumbs Up For Breakthrough Heart-Failure Device*

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