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FDA Approves ReCor's Renal Denervation System

by Reed Miller

The US FDA approved ReCor's Paradise ultrasound renal denervation system, making it the first RDN system to reach the US market. Medtronic hopes its Symplicity Spyral radiofrequency RDN system will be the second RDN system on the US market, but it may face a more difficult path through the approval process.

As expected, *ReCor Medical*'s Paradise ultrasound renal denervation system is now the first RDN system to earn US Food and Drug Administration approval.

The FDA approved Paradise as an adjunctive option for treating *hypertension* after lifestyle changes and medications have not adequately controlled the patient's blood pressure, ReCor announced late on 7 November.

Paradise is a catheter-based ultrasound-delivery device that ablates the nerves near the renal artery to attenuate sympathetic nerve activity that contributes to hypertension. Paradise also features the HydroCooling system, which circulates sterile water through the balloon catheter to protect the renal artery wall from overheating during the procedure.

ReCor's PMA for Paradise is based on the results of three sham-controlled clinical trials – *RADIANCE SOLO*, *RADIANCE TRIO*, and *RADIANCE II*. At a meeting in August, *FDA's circulatory system devices advisory panel* reviewed the results of those trials and voted to recommend that FDA approve ReCor's premarket approval (PMA) for Paradise. (Also see "*Cardio Catch-Up: Advisory Panel Gives Recor Momentum Toward US Launch Of RDN System*" - Medtech Insight, 30 Aug, 2023.)

Shortly after the panel meeting, ReCor CEO Lara Barghout told *Medtech Insight* that her company has been preparing its commercial organization to market Paradise in the US as soon as the FDA approved it. The company is also working with cardiology groups to establish the training

requirements for physicians who want to use Paradise to treat hypertension. (Also see "*News We're Watching: Philips And Walgreens Settlements, ReCor Readies For Takeoff, Farapulse Trial Results*" - Medtech Insight, 8 Sep, 2023.)

Paradise previously received CE mark and is commercially available in Europe. It is an investigational device in Japan.

Palo Alto, CA-based ReCor is a subsidiary of Otsuka Medical Devices.

What About Medtronic's RDN?

The same panel that voted in favor of ReCor's PMA for Paradise voted narrowly against recommending approval for *Medtronic*'s Symplicity Spyral radiofrequency RDN system. (Also see "*Cardio Catch-Up: Medtronic Still Has Work To Do On RDN After FDA Advisory Panel*" - Medtech Insight, 30 Aug, 2023.)

The panelists who voted against it pointed out that one of the randomized pivotal trials supporting Symplicity Spyral, *SPYRAL HTN ON MED*, missed its primary efficacy endpoint; the improvement in 24-hour systolic ambulatory blood pressure was not statistically significant.

SPYRAL HTN ON MED enrolled patients still taking anti-hypertensive medications and the trial's investigators suggested the trial may have missed its endpoint because of protocol violations in the sham-control group, which led to better-than-expected outcomes in those patients. A separate pivotal trial, *SPYRAL HTN OFF MED*, showed that RDN with Symplicity Spyral provided at least a small benefit to hypertensive patients not taking medications.

Following the panel meeting, some Wall Street analysts predicted the FDA would not approve Symplicity Spyral, while others predicted the FDA will eventually approve it – at least for a narrow indication.

"[Medtronic] remains confident in RDN and continues to have productive discussions with FDA regarding its PMA submission for its Symplicity Spyral system," Wells Fargo analyst Larry Biegelsen reported on 7 November.

He also pointed out that that ReCor submitted its PMA to the FDA in October 2022 while Medtronic submitted the PMA for Symplicity Spyral in November 2022 "So it is not surprising there was no FDA approval yet for Medtronic."