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News Release

FEops HEARTguide receives FDA clearance for LAAo planning capabilities

GENT, Belgium, April 4th 2022. FEops today announced that it received authorization from the U.S. Food and Drug Administration (FDA) for FEops HEARTguide™ pre-operative planning of left atrial appendage occlusion (LAAo) with the Abbott's Amplatzer™ Amulet™ and Boston Scientific's Watchman FLX™ device*.

FEops HEARTguide is a one-in-its-kind cloud-based procedure planning solution in the structural heart space, based on digital twin technology. With the US introduction for the LAAo workflow, FEops HEARTguide™ will enable US physicians to virtually model clinical scenarios with different implant positions and sizes of these FDA cleared LAA devices, helping the physician to select the optimal size and position for every individual patient.

"FEops HEARTguide is the new generation preoperative planning allowing operators to enter the procedure room with increased confidence for sizing and position for LAAo interventions." Said Dr Devi Nair, Director of the Electrophysiology division at St. Bernard's Heart & Vascular Center, Jonesboro, Arkansas, USA. "The platform is easy to use, very intuitive and provides critical data on how the device will interact with the LAA anatomy. The software provides implanting physicians high-quality images that enhance pre-procedure planning for proper sizing of the LAAo device and implant depth. It gives the operator the best chance to choose and implant the correct device with confidence and get it right the first time."

"FEops enabled me to select the appropriate device size and optimal device position upfront, resulting in an efficient, trouble-free, and successful ICE-guided LAAo procedure."
Said Dr Matthew Price, Director of the Cardiac Catheterization Laboratory at Scripps Clinic, La Jolla, California, USA.

"This FDA 510(k) clearance, following shortly after the FDA De Novo clearance for FEops HEARTguide LAAo workflow, is an additional milestone for FEops, allowing us to bring this innovative planning solution to the US physcians and patients for all commercially available LAAo devices". Said Matthieu De Beule, PhD, co-founder and CEO of FEops. "FEops HEARTguide was already cleared for use in the European Union, UK, Canada and Australia for the LAAo and TAVI workflows with more than 2,000 cases processed last year. We look forward to expand our innovative solution to the US market and streamline the way structural heart interventionions are planned"

*The Owner/Operator Number for this Registration is 10082838 and the listing numbers are D468597

About FEops HEARTguide™

FEops HEARTguide™ cloud-based procedure planning environment uses digital twin technology to provide clinicians and medical device manufacturers with first-ever insights into the interaction between transcatheter structural heart devices and specific patient anatomy – preoperatively. Additionally, this includes also a range of quality controlled, validated and AI-enabled anatomical analyses, which is currently available only in the European Union, UK, Canada and Australia for its TAVI and LAAo workflows. Such insights have the power to help ultimately to improve clinical outcomes in real-world hospital settings, as well as to accelerate research and development of novel device-based solutions.

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About FEops

Privately held FEops, headquartered in Gent, Belgium, is a digital health player streamlining structural heart disease management. In September 2017, FEops announced that it closed a 6 million euros financing, led by Valiance, and joined by existing investors Capricorn Partners and PMV. In December 2019, FEops has been awarded a grant of Euro 3.2 million from the European Innovation Council (EIC) accelerator programme.

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