News Release

FEops HEARTguide authorized by FDA for unprecedented LAAo planning capabilities

GENT, Belgium, October 14th 2021. FEops today announced that it received De Novo authorization from the U.S. Food and Drug Administration (FDA) for FEops HEARTguide™ pre-operative planning of left atrial appendage occlusion with the Boston Scientific WATCHMAN™ device*. FEops HEARTguide™ will enable physicians to virtually model clinical scenarios with different implant positions and sizes of the WATCHMAN™ device helping the heart team to select the optimal size and position for every individual patient.

"The preoperative insight provided by FEops HEARTguide™ is powerful and can help me to optimize decision making for selecting optimal device size and position", said Dr Jacqueline Saw, Vancouver General Hospital, Canada. "FEops HEARTguide™ is an intuitive platform I can use to discuss cases with the entire heart team to streamline my pre-op planning workflow."

"FDA authorization of FEops HEARTguide™ is a significant milestone as this is the first Interventional Cardiovascular Implant Simulation Software Device cleared on the US market," said Peter Mortier, PhD, co-founder and CTO of FEops. "Research on this technology began more than 10 years ago. We have continued to develop it with the goal of helping healthcare professionals identify the most appropriate treatment strategy for each patient precisely, safely and efficiently. This De Novo clearance is only a first step and we are already preparing for FDA 510(k) submissions for FEops HEARTguide™ LAAo workflow with Abbott's Amplatzer™ Amulet™ device and Boston Scientific's WATCHMAN FLX™ device."

*The Owner/Operator Number for this Registration is: 10082838 and the listing number: DEN200030

FEops HEARTguide™ is a one-in-its-kind procedure planning platform for structural heart interventions that provides physicians with unique insights to evaluate device sizing and positioning pre-operatively. The platform uses **digital twin** technology based on patient-specific virtual replicas of the heart. Besides the recent FDA clearance to enter the US market with its LAAo workflow with WATCHMAN™, FEops HEARTguide™ is also commercially available in the European Union, UK, Canada and Australia for its TAVI and LAAo workflows.

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. 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.

** Currently available only in the European Union, UK, Canada and Australia for its TAVI and LAAo workflows

Press Contacts

Matthieu De Beule, PhD

CEO

Tel: + 32 9 292 80 30

Email: matthieu.debeule@feops.com

About FEops

Privately held FEops, headquartered in Gent, Belgium, is a digital health player offering cloud-based procedure planning solutions in the structural heart space combining digital twin and AI technologies. 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 3.2million from the European Innovation Council (EIC) accelerator programme.

www.feops.com

-

END-