PRESS RELEASE - OERTLI INSTRUMENTE AG ACHIEVES MILESTONE WITH FDA 510(K) CLEARANCE FOR FAROS SURGICAL SYSTEM

Berneck, Switzerland – Oertli Instrumente AG, a leader in innovative surgical solutions for ophthalmology, is proud to announce the U.S. Food and Drug Administration (FDA) 510(k) clearance for the worldwide established Faros anterior cataract surgery system. This milestone underscores Oertli's global reach and commitment to providing advanced, reliable surgical equipment worldwide.

The Faros system stands out for its compact design and rapid operational readiness, requiring minimal space in operating rooms*. It is optimized for fast setup, with a readiness time of under one minute, making it ideal for integrating into office-based surgery*. Its precision in fluid or vacuum control enables adaptability to different cataract hardness, making it a versatile choice for eye surgeons.

Already proven in millions of cataract surgeries, Faros's precision, robustness, and effectiveness have contributed to reliable surgical outcomes worldwide. Its slim footprint and fast setup time can enhance operational efficiency, allowing healthcare facilities to optimize their surgical schedules.

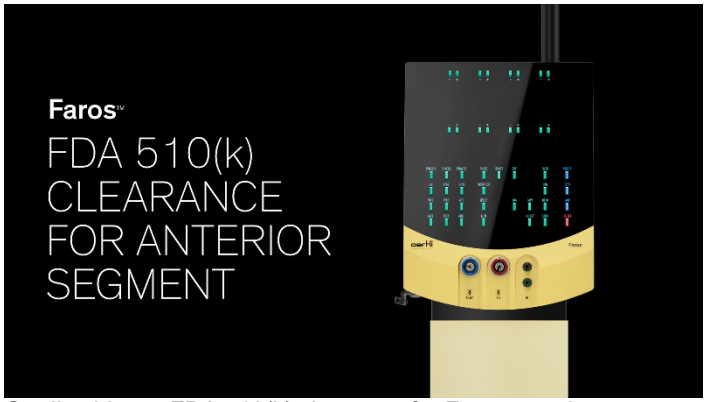
This 510(k) clearance allows the comprehensive family of Faros and CataRhex 3 devices to be almost universally available, meeting the latest safety standards, including new cybersecurity norms. The approval also includes all consumables for cataract surgery and emergency vitrectomy, ensuring that surgeons have access to a complete set of tools for eye care.

For Oertli, this approval marks another step in expanding global market coverage and highlights the company's expertise in securing worldwide approvals. Alongside Faros, the CataRhex 3 family and other Oertli products are fully approved under the European MDR regulatory framework, showcasing Oertli's commitment to compliance and safety in medical technology.

"We are excited to bring Faros to the United States, offering American ophthalmologists a system that integrates seamlessly into their operating theatres and supports the latest standards of patient care," said Thomas Bosshard, Co-CEO of Oertli Instrumente AG. "This approval is not just a certification; it's a testament to our pursuit of excellence and innovation in eye surgery."

Oertli continues to drive advancements in ophthalmic surgery, focusing on enhancing surgical precision and outcomes, reinforcing its position as a global leader in the field.

References
*Oertli data on file



Oertli achieves FDA 510(k) clearance for Faros anterior

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About Oertli Instrumente AG
Oertli develops, manufactures and markets surgical platforms, instruments and consumables that enables surgeons and OR personnel to perform cataract, glaucoma and vitreoretinal surgeries easier, safer and more efficient, thus achieving better results for their patients. With innovative developments and first-class quality, Oertli has constantly set new standards since 1955. The family-owned company develops and produces exclusively in Switzerland in the St.Gallen Rhine Valley. Oertli – Making the difference in eye surgery.

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