



First product cleared by U.S. Food & Drug Administration

Renens, 10 July 2023. Today, Lumendo announced that it has received clearance for its endodontic root canal filler from the U.S. Food & Drug Administration (FDA).¹ The FDA regulates endodontic fillers as class II medical devices, which are subject to premarket notification via the 510(k) process. Based on this clearance, Lumendo can legally market the filler for permanent root canal obturation in the U.S.A.

The FDA clearance results from a diligent, 5-year research, testing, and improvement process and excellent collaboration between the team, suppliers, and testing laboratories. It is the most important milestone the company has achieved so far and a significant step ahead in revolutionizing the way root canal treatments are done. Achieving FDA clearance in less than 2 months signifies the high standards that Lumendo adheres to, ensuring the safety and performance of all its products.

The clearance of Lumendo's flagship product has solidified its on-time commercial launch, planned for Q2 2024. By launching the world's first injectable, instant light-curable, hydrophilic endodontic filler, Lumendo aims to enable dentists and endodontists to obturate root canals with ease and confidence."

About Lumendo: Incorporated in Switzerland in 2018 as a Spin-off of the two Swiss Federal Institutes of Technology – École Polytechnique Fédéral de Lausanne (EPFL) and Eidgenössische Technische Hochschule Zürich (ETH) – Lumendo is a well-recognized upcoming disruptor in the field of endodontics. Focusing on product excellence and a strong innovation stream, the goal of Lumendo is to develop easy-to-apply, reliable, and novel products to treat unsolved medical challenges.

About the procedure: Root canal (endodontic) treatments are among the most difficult for dentists and carry the risk of application errors which can significantly reduce success rates. With more than 60 million annual treatments worldwide, it is crucial to make these treatments a success and, at the same time, optimize healthcare costs.

The platform is going to be launched in 2024 in the U.S.A.

Disclaimer: Lumendo endodontic filler is cleared for use in the U.S.A only.

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¹ FDA clearance number K231387, received 10 July 2023.