

## FDA-clearance of high-precision laser curing light

**Dübendorf, November 24, 2023** – Today, Odne announced that it has received clearance for its laser-based dental curing light (Odne®Cure) from the U.S. Food & Drug Administration (FDA).<sup>1</sup> The FDA regulates dental curing lights as class II medical devices, which are subject to premarket notification via the 510(k) pathway.

Based on this clearance, Odne can now legally market its endodontic obturation system, consisting of Odne®Fill, a light-cured root canal filling material and Odne®Cure, a high-precision laser curing light. Odne®Cure is used to irradiate the Odne®Fill after its application into the root canal. This converts the liquid Odne®Fill into a solid obturation material within seconds.

Odne's COO, Mark Bispinghoff, who was leading the development, testing, and FDA-clearance process of Odne®Cure comments: "The clearance of Odne®Cure is the result of efficient teamwork and collaboration with our partners and suppliers. It paves the way on our mission to flip the way root canal treatments are done."

The FDA clearance of Odne®Cure is a key milestone towards Odne's commercial launch, planned for April 2024 in the U.S.A. By launching the world's first injectable, instant light-curable, hydrophilic endodontic filler and the required curing light, Odne enables dentists and endodontists to obturate root canals with ease and confidence.

**About Odne:** Odne AG (formerly Lumendo AG), has its roots in a groundbreaking collaboration between two renowned Swiss institutions: The Swiss Federal Institutes of Technology in Lausanne and Zürich (EPFL & ETH Zürich). Founded in 2018, our journey began by licensing cutting-edge technology assets from these esteemed institutes.

Odne AG represents a harmonious synergy of Swiss precision and academic excellence. Our company is committed to pioneering the future of endodontics through advanced technology and innovative solutions. Endodontics, the field of dental medicine that deals with root canal treatments, has been marred by complexity and unpredictability. Odne AG is on a mission to change that.

Root canal treatments have long posed challenges for dentists, with traditionally low success rates ranging from 46% to 91%. With over 60 million annual treatments worldwide, these failures result in significant healthcare costs.

Odne's technology platform addresses these issues by offering treatment options for both dentists and their patients. Our products, slated for launch in 2024, tackle problems such as the obturation in complex morphologies.

**Disclaimer:** Odne®Fill and Odne®Cure are cleared for use in the U.S.A only. All other Odne devices are currently in development and have not received clinical approval in any jurisdiction.

For further information contact:

Odne AG, Ringstrasse 14, 8600 Dübendorf, Switzerland

[info@odne.co](mailto:info@odne.co)

[www.odne.co](http://www.odne.co)



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<sup>1</sup> FDA clearance number K232076, received 2 November 2023.