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BIOLASE and EdgeEndo Announce FDA 510(k) Clearance of New EdgePRO Laser-Assisted Microfluidic Irrigation Device for Endodontists

The EdgePRO system offers a more effective, innovative cleaning and disinfection technology for the endodontic community

FOOTHILL RANCH, Calif., Jan. 6, 2022 /PRNewswire/-- [BIOLASE, Inc.](#) (NASDAQ: BIOL), the global leader in dental lasers, and [EdgeEndo](#), a global leader in commercializing endodontic products, announced today the FDA 510(k) clearance of the [EdgePRO](#) system for endodontists seeking a more effective cleaning and disinfection alternative within root canal procedures. The new laser-assisted microfluidic irrigation device offers an advanced solution to current cleaning and disinfection techniques, without disrupting procedure workflow or adding substantial cost on a per-procedure basis.



The EdgePRO Laser-Assisted Microfluidic Irrigation device is built upon BIOLASE's patented and proven platform, Er,Cr:YSGG 2780 nm wavelength laser technology, that has been shown to provide outstanding debridement¹, cleaning, and disinfection by removing infected tissue, biofilms^{10,11}, smear layer⁵⁻⁹, and killing up to 99% of bacteria commonly found in the root canal²⁻⁴, through the combination of advanced laser light-sound technology with traditional irrigation solutions.

BIOLASE will manufacture the EdgePRO system, consumable procedure tips, and accompanying accessories for EdgeEndo, which will capitalize on their unique ability to commercialize high-quality, innovative products within the endodontic specialty. EdgeEndo will commence selling the EdgePRO system and related products immediately within the U.S. and will work closely with BIOLASE to ensure the needs of the endodontic community are satisfied with this enabling technology platform.

"This clearance enables endodontists to access state-of-the-art technology that has the potential to improve clinical outcomes and patient experiences. We remain committed to offering products and solutions that may enhance specialist skills in providing the highest quality of care for their patients while producing streamlined efficiencies for practices in a

cost-effective manner," said Dr. Charles Goodis, DDS, EdgeEndo founder, and CEO. "We are proud to partner with BIOLASE, in our combined effort to service and support the specialty with innovative and effective technologies that may elevate the quality of dental care."

"We're very pleased to complete our first OEM project, receive FDA 510(k) clearance, and deliver EdgePro units to EdgeEndo in only 12 months," adds BIOLASE President and CEO John Beaver. "This achievement is an excellent example of cross-functional teamwork between our two market-leading companies, and we look forward to our long and valuable relationship ahead."

To learn more about the new EdgePRO Laser-Assisted Microfluidic Irrigation Device EdgePro, visit edgeproendo.com. To learn more about the benefits of Waterlase technology in endodontics, visit biolase.com/betterendo.

About BIOLASE, Inc.

BIOLASE is a medical device company that develops, manufactures, markets, and sells laser systems in dentistry and medicine. BIOLASE's products advance the practice of dentistry and medicine for patients and healthcare professionals. BIOLASE's proprietary laser products incorporate approximately 271 patented and 40 patent-pending technologies designed to provide biologically and clinically superior performance with less pain and faster recovery times.

BIOLASE's innovative products provide cutting-edge technology at competitive prices to deliver superior results for dentists and patients. BIOLASE's principal products are revolutionary dental laser systems that perform a broad range of dental procedures, including cosmetic and complex surgical applications. BIOLASE has sold over 41,200 laser systems to date in over 80 countries around the world. Laser products under development address BIOLASE's core dental market and other adjacent medical and consumer applications.

For updates and information on Waterlase iPlus®, Waterlase Express™, and laser dentistry, find BIOLASE online at www.biolase.com, Facebook at www.facebook.com/biolase, Twitter at www.twitter.com/biolaseinc, Instagram at www.instagram.com/waterlase_laserdentistry, and LinkedIn at www.linkedin.com/company/biolase.

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About EdgeEndo

EdgeEndo is a medical device company with the mission to deliver high quality dental products and solutions at a substantially lower cost, which in turn benefits practitioners and patients everywhere. We are dedicated to the pursuit of bringing leading-edge products and the latest innovations to the industry. This thoughtful and modern business model is revolutionizing dental practices across the U.S. and the world.

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