

Envista Obtains FDA Clearance for Assisted Intelligence Mandibular Nerve Tracing

BREA, Calif., March 28, 2022 /[PRNewswire](#)/ -- Envista Holdings Corporation (NYSE: NVST) ("Envista") -- Envista announced today the 510(k) Food and Drug Administration (FDA) clearance of its Assisted Intelligence (AI) mandibular nerve tracing feature in its image acquisition and diagnostic software platform DTX Studio Clinic.

The tracing of the mandibular nerve in modern dentistry is of high significance as it influences the available therapeutic options for the patient. The proper visualization of the nerve can prevent complications. When done manually, it is a task that can be both time-consuming and error prone. DTX's AI capabilities supports clinicians as they perform this important task.

This clearance complements a series of AI-powered functionality in DTX Studio Clinic. In 2017, Envista obtained FDA clearance for its AI-driven 3D virtual tooth setup algorithm. In 2020, a further clearance was received for automatic tooth position identification and automated sorting of full-mouth x-ray series. On March 25, the FDA cleared the third AI-focused 510(k) for the fully automated mandibular nerve tracing on CBCT scans.

Amir Aghdaei, Envista CEO, said, "This clearance is another important step towards our digital strategy of expanding the capabilities of our powerful, unified, and open dental diagnostic software platform DTX Studio Clinic. With its combination of a user-friendly interface and AI-driven functionality, DTX Studio Clinic reduces the time clinicians spend on time-consuming tasks, while simultaneously helping

prevent complications and enabling increased focus on the patient. We are particularly proud of our fully automated mandibular nerve tracing functionality with its high clinical relevance for dental implant-based patient rehabilitations."

About Envista Holdings Corporation

Envista is a global family of more than 30 trusted dental brands, including Nobel Biocare, Ormco, DEXIS, and Kerr united by a shared purpose: to partner with professionals to improve lives. Envista helps its customers deliver the best possible patient care through industry-leading dental consumables, solutions, technology, and services. Our comprehensive portfolio, including dental implants and treatment options, orthodontics, and digital imaging technologies, covers a broad range of dentists' clinical needs for diagnosing, treating, and preventing dental conditions as well as improving the aesthetics of the human smile. With a foundation comprised of the proven Envista Business System (EBS) methodology, an experienced leadership team, and a strong culture grounded in continuous improvement, commitment to innovation, and deep customer focus, Envista is well equipped to meet the end-to-end needs of dental professionals worldwide. Envista is one of the largest global dental products companies, with significant market positions in some of the most attractive segments of the dental products industry. For more information, please visit www.envistaco.com.

For Further Information

Stephen Keller
Investor Relations
Envista Holdings Corporation
200 S. Kraemer Blvd., Building E
Brea, CA 92821
Telephone: (714) 817-7000

Fax: (714) 817-5450

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