

Nobel Biocare Receives FDA 510(k) Clearance for the Nobel Biocare N1™ Implant System

BREA, Calif., Dec. 27, 2021 /[PRNewswire](#)/ -- Envista Holdings Corporation (NYSE: NVST) ("Envista") today announced that the U.S. Food and Drug Administration (FDA) has cleared the Nobel Biocare N1™ implant system. Boasting a biologically driven design of components and forward-thinking treatment protocols, the N1™ implant system represents a significant step forward in patient-centric implant solutions.

More than an implant, N1 is a comprehensive system of dedicated instruments, prosthetic components, and surgical protocols. New features of the system include an implant designed for immediate placement and predictable insertion torques, a trioval conical connection for the abutment to slide into place, and an emergence profile designed for soft tissue maintenance.

Innovative site preparation for greater patient comfort

The Nobel Biocare N1™ system includes the novel feature of the OsseoShaper™, an instrument that redefines site preparation and is set to reshape implantology with optimized workflows, greater patient comfort and faster treatment times. By gently 'shaping' the osteotomy at low speed and without irrigation, the OsseoShaper™ reduces noise and vibration compared to conventional drilling protocols. This leads to improved patient comfort and has been shown in pre-clinical studies to preserve vital bone.

Embracing surface chemistry and digital workflows

Fully embracing the new Mucointegration™ concept, the Nobel Biocare N1™ features the Xeal™ and TiUltra™ surface

treatments. With their specially tailored surface chemistry and topography, TiUltra implants and Xeal abutments can benefit from this design to optimize tissue integration at every level. Nobel Biocare N1™ will be further integrated into the digital workflow with the DTX Studio™ suite, giving dental professionals more opportunities to provide patients with shorter time to teeth.

Amir Aghdaei, Chief Executive Officer, Envista, stated, "For over 50 years, Nobel Biocare has been a pioneering force behind implantology. The demand for high quality patient-centric solutions is higher than ever, and the Nobel Biocare N1™ system enables clinicians to set a new standard in personalizing, digitizing, and democratizing the implant treatment experience they can offer patients."

Patrik Eriksson, President Nobel Biocare, explained, "Drilling protocols have hardly changed over the past 50 years. However, the OsseoShaper™ provides a completely new approach designed for patient comfort, streamlined workflow, and improved predictability; while at the same time, respects biology to achieve fast osseointegration. We are excited to partner with clinicians to bring the N1 system to US-based patients."

About Nobel Biocare

Nobel Biocare is a world leader in the field of innovative implant-based dental restorations. The company's portfolio offers solutions from single tooth to fully edentulous indications with dental implant systems (including key brands NobelActive® and NobelParallel™ and ceramic implant NobelPearl™*) a comprehensive range of high-precision individualized prosthetics and CAD/CAM systems (NobelProcera®), digital solutions for treatment planning and guided surgery (NobelClinician® and DTX Studio™ suite) as

well as biomaterials. Nobel Biocare supports its customers through all phases of professional development, offering world-class training and education along with practice support and patient information materials. The company is headquartered in Zurich, Switzerland. Production takes place at five sites located in the United States, Sweden, and Germany. Products and services are available in over 80 countries through subsidiaries and distributors.

*Distributed by Nobel Biocare. Manufactured by Dentalpoint AG

About Envista

Envista is a global family of more than 30 trusted dental brands, including KaVo, Kerr, Nobel Biocare, and Ormco, 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 an estimated 90% 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.

Forward-Looking Statements

Certain statements in this press release are "forward-looking" statements within the meaning of the federal securities laws. There are a number of important factors that could cause actual results, developments and business decisions to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include, among other things, the impact of the COVID-19 pandemic, including new variants of the virus, the pace of recovery in the markets in which we operate, the conditions in the U.S. and global economy, the markets served by us and the financial markets, the impact of our debt obligations on our operations and liquidity, developments and uncertainties in trade policies and regulations, contractions or growth rates and cyclicity of markets we serve, fluctuations in inventory of our distributors and customers, loss of a key distributor, our relationships with and the performance of our channel partners, competition, our ability to develop and successfully market new products and services, the potential for improper conduct by our employees, agents or business partners, our compliance with applicable laws and regulations (including regulations relating to medical devices and the health care industry), the results of our clinical trials and perceptions thereof, penalties associated with any off-label marketing of our products, modifications to our products that require new marketing clearances or authorizations, our ability to effectively address cost reductions and other changes in the health care industry, our ability to successfully identify and consummate appropriate acquisitions and strategic investments, our ability to integrate the businesses we acquire and achieve the anticipated benefits of such acquisitions, contingent liabilities relating to acquisitions, investments and divestitures, significant restrictions and/or potential liability based on tax implications of transactions

with Danaher, security breaches or other disruptions of our information technology systems or violations of data privacy laws, our ability to adequately protect our intellectual property, the impact of our restructuring activities on our ability to grow, risks relating to currency exchange rates, changes in tax laws applicable to multinational companies, litigation and other contingent liabilities including intellectual property and environmental, health and safety matters, risks relating to product, service or software defects, risks relating to product manufacturing, commodity costs and surcharges, our ability to adjust purchases and manufacturing capacity to reflect market conditions, reliance on sole or limited sources of supply, the impact of regulation on demand for our products and services, labor matters, international economic, political, legal, compliance and business factors, and disruptions relating to war, terrorism, widespread protests and civil unrest, man-made and natural disasters, public health issues and other events. Additional information regarding the factors that may cause actual results to differ materially from these forward-looking statements is available in our SEC filings, including our Annual Report on Form 10-K for fiscal year 2020 and our Quarterly reports on Form 10-Q. These forward-looking statements speak only as of the date of this press release and except to the extent required by applicable law, we do not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise.

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