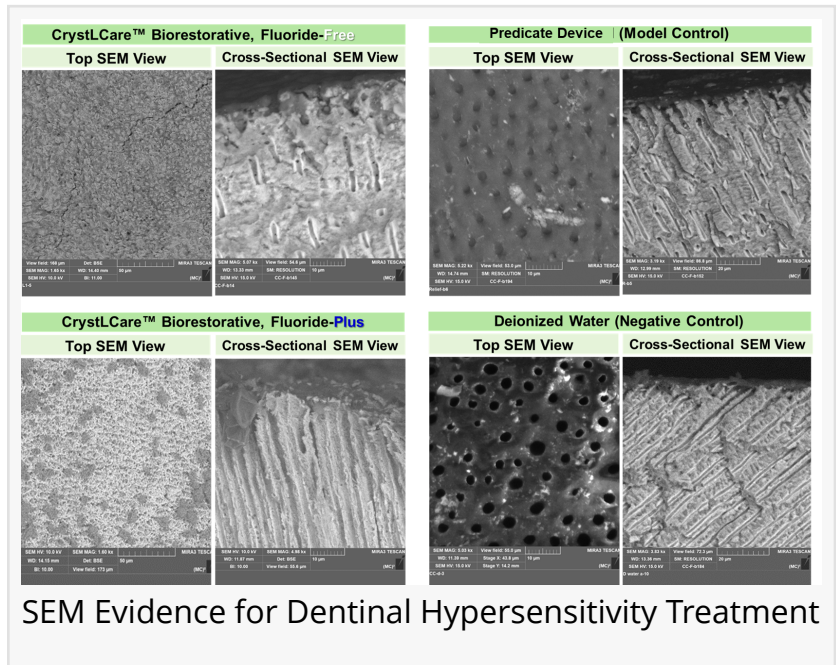


GreenMark Secures FDA Clearance for CrystLCare™ PRO Biorestorative

GreenMark secured FDA clearance to market CrystLCare™ PRO as a 510(k) Class II Medical Device to promote natural tooth repair and relieve dental sensitivity.

ANN ARBOR, MI, UNITED STATES, January 7, 2025 /EINPresswire.com/ -- GreenMark Biomedical Inc., a pioneer in leveraging biomimetic technology for dental health innovations, today announced that the company has secured regulatory clearance from the U.S. Food and Drug Administration (FDA) to market its CrystLCare™ PRO Biorestorative, Fluoride-Plus product as a 510(k) Class II Medical Device.



This innovative solution represents the next advancement in GreenMark’s suite of dental care products, designed to promote natural tooth repair and relieve dental sensitivity.



The technology offers a more fluoride-efficient solution, requiring less fluoride than traditional products, and provides a non-fluoride alternative for those seeking fluoride-free care."

*Dr. Nathan A. Jones, M.Sc.,
Ph.D., Vice President
Technology at GreenMark*

CrystLCare™ PRO utilizes GreenMark’s patented bioresorbable, mineral-loaded starch particles to deliver bioactive calcium and phosphate ions directly to enamel porosities and dentinal tubules by targeting the subsurface of teeth. These ions form apatite crystals, the primary component of enamel and dentin, supporting the natural repair of damaged dental tissues. Developed through an NIH-funded collaboration, this breakthrough technology is transforming oral care.

Following the 2024 launch of CrystLCare™ Biorestorative, Fluoride-Free in partnership with Dentulu, Inc., CrystLCare™ PRO is the second in GreenMark’s

biorestorative portfolio. The fluoride-free and fluoride-plus solutions target dental sensitivity while promoting oral health. The new product for in-office use by dental professionals is expected to be available in three months.

Dr. Nathan A. Jones, M.Sc., Ph.D., co-inventor and Vice President Technology at GreenMark, highlighted the convenience of the company's dental strips: "Our fully dissolvable strips are applied directly onto your teeth to which they instantly adhere. The technology offers a more fluoride-efficient solution, requiring less fluoride than traditional products, and provides a non-fluoride alternative for those seeking fluoride-free care."

Dr. Wendy Bloembergen, MD, MS, Vice President Clinical Affairs, explained the underlying causes of dental sensitivity: "Sensitivity arises from the loss of dentin's protective covering, enamel or cementum, due to factors such as gingival recession, abrasion, erosion, caries, or other predisposing factors. This leaves dentinal tubules exposed, canals that radiate outward from the pulp cavity, allowing external stimuli like temperature or pressure to trigger pain by stimulating nerves in the pulp cavity."

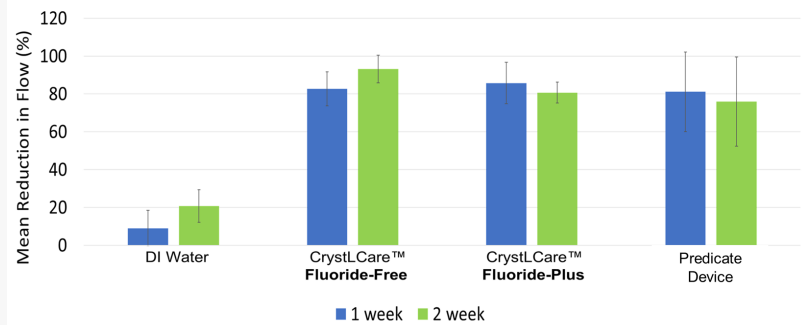
Dr. Arash Hakhamian, DDS, FICOI, FIADFE, CEO of Dentulu, noted the widespread need for solutions like

CrystLCare™ PRO: "Procedures like scaling, root planing, temporary & permanent crown placement, veneers, bridge work, and even teeth whitening agents can lead to severe sensitivity by exposing dentin or allowing peroxide molecules to irritate nerves. CrystLCare™ PRO equips dental professionals with an effective tool to improve outcomes, minimize discomfort, and reduce the need for sedation during treatments."

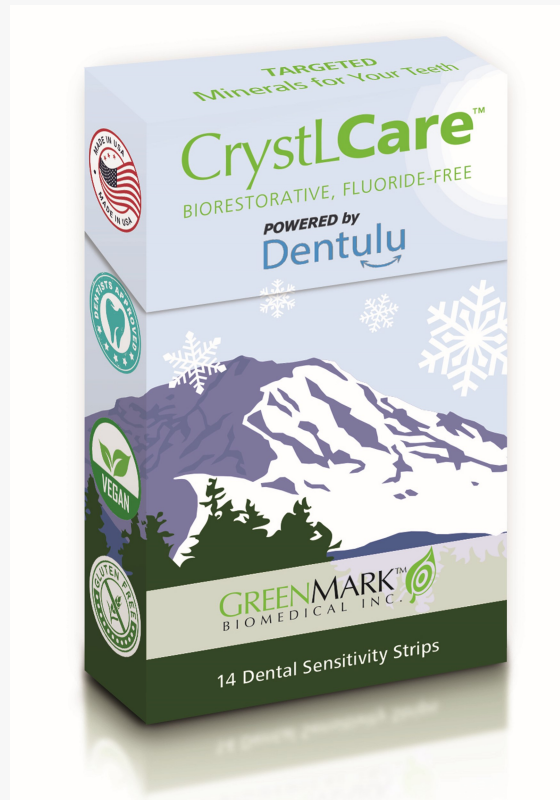
3rd Party Hydraulic Conductance on Dentin Disks

Single dose on Day 1 – then 2 Weeks in Saliva

Mean Percentage Reduction in Fluid Flow, by Treatment Time and Type (Pashley Model)



Third-Party test results using Hydraulic Conductance on Dentin Disks



CrystLCare™ Biorestorative, Fluoride-Free 14-dose fliptop pack

Dr. Steven Bloembergen, Ph.D., founder, Chairman and CEO of GreenMark, emphasized the broader implications for oral health: "There is a well-established connection between oral and systemic health. At GreenMark we are committed to making dental check-ups a more positive experience for patients and dental professionals alike while advancing better health outcomes."

GreenMark Biomedical continues to innovate in minimally invasive dental care, offering groundbreaking solutions that address unmet needs in oral health.

About GreenMark Biomedical Inc.

GreenMark is dedicated to transforming dental care through scientific innovation and technological excellence by developing a systems approach for treatment of dental sensitivity and management of caries (dental decay), with its patented products that involve sub-micron particles produced from food-grade starch, an ideal carrier since enzymes in saliva degrade starch. Dental sensitivity affects up to 74% of Americans, and caries is the most prevalent chronic disease in the world, affecting more than 95% of Americans over their lifetimes. GreenMark's team has demonstrated the ability to load calcium and phosphate, the essential mineral components of dentin and enamel, inside its small starch particles, and has been developing treatment products designed to target and restore minerals to the teeth. GreenMark has also developed methods to identify, better assess and monitor caries disease in its earliest stages, before being detected on X-Ray. The company's LumiCare™ Caries Detection Rinse and half-dose LumiKids™ rinse for ages 6 to 11, contain fluorescently-labeled particles that target the porous subsurface of caries lesions in enamel and illuminate them using a dental curing light, thereby aiding in their visualization. The identification at early stages before a cavity forms, allows the use of preventive non-surgical management options, resulting in less discomfort and improved long-term oral health outcomes for patients. Visit www.greenmark.bio.

About Dentulu, Inc.

Dentulu is the leading provider of virtual and Teledentistry solutions, offering innovative services that make dental care accessible to everyone under the supervision of licensed Dentists. Dentulu's platform facilitates a wide range of dental services directly to homes and workplaces, transforming the way dental care is delivered. Dentulu's focus is on providing minimally invasive, preventative dental services to millions of patients nationwide utilizing its growing network of Teledentists. Visit www.dentulu.com.

For more information on CrystLLCare™ Biorestorative strips and related noninvasive products, visit the websites of GreenMark and its partner Dentulu, Inc. at www.greenmark.bio and www.dentulu.com.

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