

TARGETED REMINERALIZATION TREATMENT USING MINERAL LOADED STARCH NANOPARTICLE



**Steven Bloembergen,
PhD**

GreenMark
Biomedical Inc.

Clinical Need – Over \$200 billion is spent globally on dental caries and its complications, the most prevalent chronic disease worldwide. The unmet clinical need is atraumatic treatment of caries through subsurface remineralization of enamel, as current high fluoride toothpastes and varnishes incompletely repair carious lesions. Our products treat both hypersensitivity and early-stage caries, to reduce discomfort, preserve precious enamel and improve oral health.

Solution – Our research has shown enamel lesions are negatively charged. We produce particles less than 400 nm in size from food-grade starch that have a positive charge, and load them with the enamel minerals, to target the subsurface and release minerals inside the lesion. In-situ degradation in saliva takes care of the rest. Our products, CrystLCare™ Biorestorative Fluoride-Free and Fluoride-Plus, are packaged in dry form and instantly disperse in less than a minute at time of treatment.

Competitive Advantage – While traditional fluoride treatments merely impact the extreme surface layer of enamel lesions, targeting the dominant subsurface lesion will enable a superior non-surgical dental treatment. Localized concentration of minerals and fluoride facilitate tooth structure regeneration through formation of apatite-like crystals, yielding superior remineralization of lesions compared to other available treatments.

ITP Support – Challenges led to innovation and easy-to-use dispersible film packaging. An AI-driven camera under development has shown correlation with mineral density and caries severity (Caries Research, 2022), supporting utility in future clinical studies. Dentinal occlusion was demonstrated by third-party testing. Two X-ray methods proved occluding material is mineral based, and remineralization is regenerating the apatite crystal structure. All third-party biocompatibility safety and biological risk assessments passed.

FOUNDATIONAL PUBLICATION

Jones et al. Nanoparticle-Based Targeting and Detection of Microcavities. Adv Healthc Mater 2017

INTELLECTUAL PROPERTY

US10,987,434 Detection and Treatment of Caries and Microcavities with Nanoparticles

ANTICIPATED REGULATORY PATHWAY

Device: 1) Class I, 2) 510(k) Class II, 3) de novo Class II

ANTICIPATED COMMERCIALIZATION STRATEGY

Direct sales force currently being developed

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