

Targeted Remineralization Treatment Using Mineral Loaded Starch Nanoparticles

Clinical Need

Dental caries is the most prevalent chronic disease worldwide. The unmet clinical need is noninvasive treatment through subsurface remineralization of enamel, as current fluoride toothpastes & varnishes incompletely repair caries lesions. Our professional-use products treat both dental hypersensitivity and early-stage caries, to reduce discomfort, preserve precious enamel and improve oral health.

Solution

We produce tiny positively charged, mineral-loaded starch particles, to target and release inside negatively charged tooth subsurfaces. In-situ degradation forms hydroxyapatite crystals, occluding dentinal tubules and enamel porosities. Our products, CrystLCare™ Biorestorative, Fluoride-Free and Fluoride-Plus, are easy-to-use dissolvable dental strips, 14 single-use doses in a Fliptop Pack.

Competitive Advantage

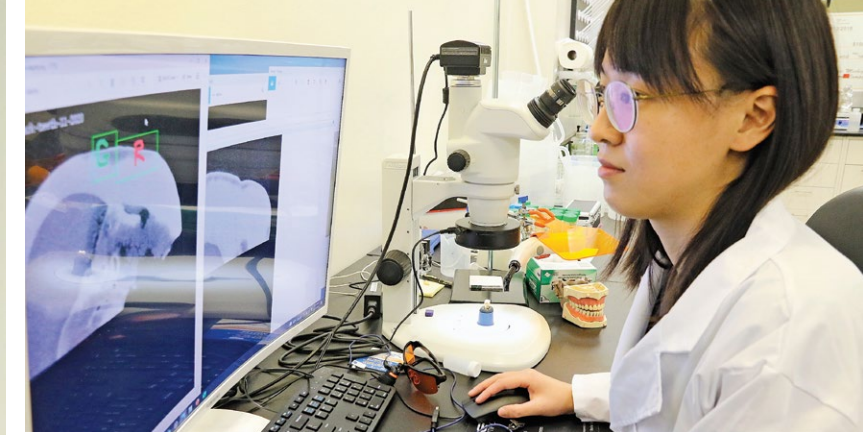
Current fluoride products merely seal the extreme upper surface layer of enamel lesions, but targeting the subsurface enables non-surgical treatment of early-stage caries as well as sensitivity relief. Localized concentration of minerals and fluoride facilitates tooth structure regeneration through formation of apatite crystals, yielding superior treatment compared to currently available products.

Foundational Publications & Patents

- Jones et al. Nanoparticle-based targeting and detection of microcavities. [Adv Healthc Mater 2017](#)
- Amaechi et al. Evaluation of a Novel Caries Detecting Oral Rinse. [BDJ Open 2023](#)
- [US10,987,434](#) Detection and Treatment of Caries and Microcavities with Nanoparticles



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ITP Support

The project entered into the ITP program in 2018, and since then, the program has supported the subsurface treatment concept based on targeted illumination with companion caries detection product, as well as the validation of treatment performance and safety, and implementation of medical device requirements and operations. GreenMark Biomedical, a 2016 “NewCo”, proposed its subsurface treatment based on targeted illumination with the companion LumiCare™ caries detection product. With support from the program, GreenMark established proof-of-concept, developed two CrystLCare™ products, demonstrated occlusion of dentinal tubules and enamel porosities, validated safety, scaled manufacturing & packaging, implemented Quality systems and a Device Master Record.

Key Inflection Points/ Regulatory Pathway

- Secure Series A and initiate clinical studies for CrystLCare™ Biorestorative Remin products in 2023
- Further scale up manufacturing of the CrystLCare™ products in 2023-2024
- Secure regulatory clearance for CrystLCare™ Biorestorative, Fluoride-Plus DH product in 2023-2024
- CrystLCare™ Biorestorative, Fluoride-Free product: Class I Medical Device FDA-registered
- CrystLCare™ Biorestorative, F-Plus: 1) 510(k) Class II/Fluoride Monograph, 2) De Novo Class II

Opportunities for Partnerships

- Seeking strategic partnership with global dental supply company and/or distributors
- Raising \$10+ million Series A equity investment round

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