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3-D Matrix, Ltd.

Clinical trial started in U.S. about dental implant product "Alveolar Rebuilding TDM-711"

3-D Matrix. Inc. (3DM US), a consolidated subsidiary of 3-D Matrix, Ltd. (3DM Japan), has Investigational Device Exemption (IDE) Approval from Food and Drug Administration (FDA) about dental implant product "Alveolar Rebuilding" (develop code: TDM-711) regarding self-assembly peptide technique which 3DM US has an exclusive license of from Massachusetts Institute of Technology (MIT); The first participant was enrolled and the first operation was conducted recently. We continue participants enrollment.

This clinical trial is conducted at Forsyth Institute, a research institute of medical and dental school of Harvard University, as a medical device since TDM-711 is applied in "medical device" category.

Self-assembly gel peptide, which maintains three-dimensional structure with nanofiber, resembles the circumstance where cells grow in vivo and has a feature supporting renewal of body tissue; therefore, TDM-711 filled in bone loss places promotes bone renewal as scaffolding. Also, this peptide has no risk of infection with hepatitis C virus by raw materials since it is made by chemical synthesis without animal derived materials.

In dental implant operations, it is said that 10-15% of patients who want implant placements have lacking alveolar bone and need to rebuild alveolar. In the U.S., alveolar rebuild operations with alternative bone such as Allograft or xenogeneic bone (animal bone) are established procedures, which are operated in 1.5 million cases per year and have a growing market.

3DM Japan is going to promote to develop this technology for commercialization and seek sales partners in U.S. to have a strong position of the market.

This clinical trial does not influence the earning forecast of 3DM Japan at this moment.