



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



Certificate of Class I

Awarded to

Megagen Implant Co., Ltd.

377-2 Gyocheon-Ri, Jain-Myeon, Gyeongsan-Si, South Korea

Listing Number: E220672

Registration Number: 3005554774

This is to certify that Lateral Sinus Graft System has been registered with the U.S. FDA and it is safe for marketing in the United States of America.

Indications for Use: Lateral Sinus Graft System is required to make sufficient bone in height and width prior to dental implant surgery especially dental implant surgery on the maxilla needs sufficient bone in vertical height to hold dental implant in place. Therefore sinus membrane elevation makes enough space to place dental implant and increase initial stability using lateral sinus graft system.

Product Class: Accessories, Implant, Dental, Endosseous

Product Code: NDP

Trade Name: Lateral Sinus Graft System

Regulation Number: 21 CFR 872.3980

Regulatory Class: Class I

FDA Registered Date: Aug 5, 2010

Presented by: Official Correspondent, Consultant and U.S. FDA Designated Agent



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