



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



*Certificate of Class I*

*Awarded to*

**Megagen Implant Co., Ltd.**

472, Hanjanggun-ro, Jain-myeon, Gyeongsan-si, South Korea, 712-852

**Listing Number: E220672**

**Registration Number: 3005554774**

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

**Indications for Use:** Prior to dental implant surgery, it is required to make sufficient bone in height and width.  
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 MICAkut.

**Product Class:** Accessories, Implant, Dental, Endosseous

**Product Code:** NDP

**Trade Name:** MICAkut

**Regulation Number:** 21 CFR 872.3980

**Regulatory Class:** Class I

**FDA Registered Date:** Dec 17, 2012

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



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