



## Certificate of 510(k) Awarded to

## Megagen Implant Co., Ltd.

377-2 Kyochon-ri, Jain-myun, Gyeongsan, Gyeongbuk, KOREA (post code: 712-852)

## 510(k) Premarket Notification Number: K090950

This is to certify that Bone Plus<sup>TM</sup> BCP has been evaluated for product safety and efficacy by the U.S. FDA and cleared for marketing in the United States of America.

Indications for Use: Bone Plus™ BCP is intended to fill, augment, or reconstruct

periodontal or bony defects of the oral and maxillofacial region

Trade/Device Name: Bone Plus<sup>TM</sup> BCP

**Regulation Number: 21 CFR 872.3930** 

**Regulation Name:** Bone Grafting Material

**Regulatory Class:** Class II

**Product Code:** LYC

FDA Approval Date: July 2, 2010

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



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