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 **Bone Expander Surgical Kit** has been registered with the U.S. FDA and it is safe for marketing in the United States of America.

Indications for Use: Bone Expander and Split Chisel are intended to gradually expand and condense the bone to prepare the dental implant insertion without the bone loss in case of the atrophic thin ridge and low density bone such as D4 bone. There are several methods of techniques to prepare implant sites into the bone to expand the atrophic thin ridge bone. Carrying the force by the surgical mallet is not well tolerated by patients, and using a surgical drill also has a risk of the thin ridge bone. In contrast, Bone Expander and Split Chisel decrease the surgical trauma such as the fracture of bone, the reason why the double thread of Bone Expander gradually widens and compresses the thin ridge bone without the bone loss, and the flat tip of Split Chisel prevents the excessive expansion of the bone. Thus those tools improve the clinical success by increasing initial stability and maintaining bone density stable through the compressed high density bone by condensing the surrounding bone.

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Product Class:	Accessories, Implant, Dental, Endosseous
Product Code:	NDP
Trade Name:	**Bone Expander Surgical Kit**
Regulation Number:	21 CFR 872.3980
Regulatory Class:	Class I
FDA Registered Date:	February 3rd, 2012

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

KoDent

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