



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 Abutment Selection Guide Kit has been registered with the U.S. FDA and it is safe for marketing in the United States of America.

Indications for Use:

Abutment Selection Guide is intended to estimate the height of gingival, and adjust the height or angle of the dental prosthetics which is the cement retained type. The unsuitable selection of the abutment causes the surgery failure. Abutment Selection Guide helps to decrease the failure by predetermining the optimal abutment, and enable a fast selection of angle, diameter, and abutment height. There are two types, which are Straight type and Angle type. Straight type (EZ Post Guide) helps to select Solid Abutment or EZ Post, and Angle type (Angled Abutment Guide) helps to select Angled Abutment. They are not screw-fixed but merely placed prior to inserting of the final abutment. There are different colors according to the cuff height. They have a handle on the top of the post to hold easily. There is a hole of the number-shaped on the handle to stand for the profile diameter, and to prevent the patient from swallowing Abutment Selection Guide by passing a suture thread through the hole.

Product Class: Accessories, Implant, Dental, Endosseous
Product Code: NDP
Trade Name: **Abutment Selection Guide Kit**
Regulation Number: 21 CFR 872.3980
Regulatory Class: Class I
FDA Registered Date: February 14th, 2012

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



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