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, GYEONGSANGBUGDO,
712-852, KOREA, REPUBLIC OF

Listing Number: E220672
Registration Number: 3005554774

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

Indications for Use:	AnyGuide Kit is intended to perform a flapless implant surgery using a surgical guide constructed following computerized 3D planning of a pre-operative CT scan. The conventional implant surgery via panoramic x-ray images is difficult to perform the precise surgery. It is incision surgery using a blade with bleeding and pain, and also takes long time for operation and healing. In contrast, the flapless implant surgery is the type of implant surgery where incisions are not utilized during the surgery. The flapless implant surgery using a dental computed tomography (dental CT), dental implant diagnosis program (SimPlant), and surgical guide can be executed accurately and precisely as planned. The use of digital scans and computer guided implant placement techniques has allowed clinicians to be able to place dental implants directly through the gums without the need to visualize the bone. And also the flapless implant surgery allows for faster healing, less inflammation and less post-operative discomfort and pain.
Product Class:	Accessories, Implant, Dental, Endosseous
Product Code:	NDP
Trade Name:	**AnyGuide Kit**
Regulation Number:	21 CFR 872.3980
Regulatory Class:	Class I
FDA Registered Date:	May 29, 2012

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

KoDent

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