MegaGen Implant Co., Ltd.
℅ Mr. Dave Kim
President
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

June 26, 2019

Re: K190096
Trade/Device Name: R2GATE
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 4, 2019
Received: June 4, 2019

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190096

Device Name
R2GATE

Indications for Use *(Describe)*

R2GATE is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CBCT scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

K190096

R2GATE Picture Archiving and Communication System

1. Submitter Information**:**

MEGAGEN IMPLANT CO., LTD
41940, 10F, 12 Gong Pyeong Ro
Jung Gu Daegu, 41940
Republic of Korea

Contact Person: HyeJin Jung
Telephone Number: +82-70-4352-1120
Fax Number: +82-70-7469-1120

Date Prepared: 1/13/2019

2. Device Name:

Proprietary Name:	R2GATE
Classification Name:	Picture Archiving and Communication System
CFR Number:	21 CFR §892.2050
Device Class:	Class II
Product Code:	LLZ

3. Predicate Device:

Trade/Device Name:	Blue Sky Bio Plan
510k Number:	K090607
Regulation Number:	21 CFR 892.2050
Regulation Name:	Picture archiving and communications system
Regulatory Class:	Class II
Product Code:	LLZ.

4. Description of Device:

R2GATE is a web application and is intended for pre-operative planning to create and review plans for dental implant placement and surgical treatment, using MEGAGEN Implants. A dental implant plan can be edited with R2GATE Editor, a desktop software application, by a licensed dentist with clinical experience in implant surgery and medical image review.

The implant surgery plan can be used for manufacturing a surgical guide or for evaluation of treatment options by a licensed dentist.

5. Indications for Use:

R2GATE is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CBCT scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.

6. Substantial Equivalence:

Table 6-1 Substantial equivalence comparison table

Criteria	Predicate Devices	Device under Consideration	Equivalency
Element of Comparison	Blue Sky Bio, LLC (K090607)	MegaGen Implant Co., Ltd,	
Device Name	Blue Sky Bio Plan	R2GATE Windows	
Intended Use	Review and approve implant plan, Edit implant plan for approval in online case review.	Create, edit and approve implant plan. For approval in online case review.	Same
Indications for Use	Blue Sky Plan is intended to be used as conversion software for Computed Tomography (CT) generated DICOM images into a format that allows a dentist to assess the anatomic topography of the maxilla and mandible as well as location of important structures. It allows the information to be used for pre- surgical treatment planning of dental implant procedures. The Blue Sky Plan software is deployed on standard personal computer hardware using a Windows operating system.	R2GATE is intended for use as a software interface and image segmentation system for the transfer of imaging information from a CBCT scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.	Same
Media for Delivery	- Software-File for download	- Software-File for download	Same
Principles of operation	Online software application Desktop software application	Online software application Desktop software application	Same
Program language	C# C++	C# C++	Same
Operating System	Windows	Windows	Same
software functionalities			
Reorientation	Reorientation function to change the direction of the CT image on display.	Reorientation function to change the direction of the CT image on display.	Same
Nerve canal	Create a nerve carnal tracing model using the tools provided on the 2D image. The cross section of the model is displayed as a 3D image on the volumetric rendering view.	Create a nerve carnal tracing model using the tools provided on the 2D image. The cross section of the model is displayed as a 3D image on the volumetric rendering view.	Same
3D model scan implant planning	The scanned 3D model (STL file) can be reconstructed and used for implant planning.	The scanned 3D model (STL file) can be reconstructed and used for implant	Same
Image processing	Change the image displayed on the 2D or 3D screen using a tool provided by the program.	Change the image displayed on the 2D or 3D screen using a tool provided by the program.	Same
Printing output	Output data that can be used for implant surgical guide fabrication.	Output data that can be used for implant surgical guide fabrication.	Same
Output compatibility	The STL file generated can be loaded form other software in conformity with the standard.	The STL file generated can be loaded form other software in conformity with the standard.	Same
Screenshot	A screen view on a program can be stored as an image file.	A screen view on a program can be stored as an image file..	Same

Measurement Tools	Measure the angle and length on a 2D screen using the tool available in the program. Measure the length using 2 points and measure the angle between the two line segments using 3 points.	Measure the angle and length on a 2D screen using the tool available in the program. Measure the length using 2 points and measure the angle between the two line segments using 3 points.	Same
Implant Control	Implant model can be added, deleted, moved and rotated on the screen. Only the implant models in the implant library can be used.	Implant model can be added, deleted, moved and rotated on the screen. Only the implant models in the implant library can be used.	Same
Anchor pin Control	Anchor-pins can be added, deleted, moved and rotated on the screen. The user may use the product provided by the program or enter the diameter and length setting.	Anchor-pins can be added, deleted, moved and rotated on the screen. The user may use the product provided by the program only.	Same
Cephalo analysis	The user can set points of the analysis using the cephalon analysis method provided by the program..	The user can set points of the analysis using the cephalon analysis method provided by the program..	Same
2D Image View	The CT image data can be loaded for axial, coronal, sagittal, cross section and panorama view mode.	The CT image data can be loaded for axial, coronal, sagittal, cross section and panorama view mode.	Same
STL file Management	Load a STL file or save a 3D model created in the program as an STL file.	Load a STL file or save a 3D model created in the program as an STL file.	Same
View Management	2D/3D view can be zoomed, moved, rotated.	2D/3D view can be zoomed, moved, rotated.	Same
Project Management	Proceed to a new project. Save the current project or recall the previous project.	Proceed to a new project. Save the current project or recall the previous project..	Same
Wax Up Fabrication	Create the desired model by adjusting the position, size, and direction of the basic wax up model provided by the program.	No function to make a wax up model	Difference
Surgical Guide Fabrication	Using the virtual STL model and implant model, the surgical guide is constructed as a point-set area on the surface of the STL model.	This SW does not provide the surgical guide fabrication function.	Difference
Report Template	Includes a report template via PDF export and print setting. A screen shot can be saved for display.	No report document template. A screen shot can be saved for display.	Partially equivalent
Printing Output	Dental Surgical Guide	Dental Surgical Guide	Same
Output Compatibility	Compatible with dental 3D printers, milling machines and CAM equipment that support the STL file format.	Compatible with dental 3D printers, milling machines and CAM equipment that support the STL file format.	Same

Analysis of differences

The proposed device has similar indications for use and mostly same basic functionalities in comparison with the predicate device. The functions, view, and module for both the subject and predicate device are used for review of radiographic images, creation of a dental treatment plan and implant surgical guide. The differences include the proposed implant devices that each program depends on. For an implant surgical guide and treatment simulation, R2GATE utilizes a pre-loaded implant device library featuring MEGAGEN IMPLANT family whereas Blue Sky Bio may have different implant library other than MEGAGEN Implant.

7. Software testing

Software verification and validation was conducted to ensure the functionality and compatibility of all system components and to support the safety and effectiveness of the proposed devices.

The verification and validation tests consist of the following activities:

- Unit test
- Peer Code Review
- Integration test
- Internal release test
- Formal system test
- Acceptance test

Verification and validation tests confirm that all user needs and SW performance requirements are fulfilled according to the design input.

Also the following comparison tests confirm the functionality, safety and efficacy of the proposed devices.

8. Non-Clinical Performance Data

Non-clinical tests have been developed in-house including acceptance criteria. The test results demonstrated substantial equivalence between the subject device and the predicate device. (Document No: R2W-D34-PER-001)

(i) Validation of CBCT data (DICOM Image Data): Physical measurement values and numerical values (Hounsfield unit, HU) of distance and angle between specific points of CBCT data of R2GATE Windows and Blue Sky Plan Software. The distance and angle value between the Blue Sky Plan and R2GATE Windows were measured within the acceptable range

(ii) Verification of integrity of CBCT data (DICOM Image Data): Experiments on modification of CBCT data of R2GATE Windows and Blue Sky Plan Software. There is no modification or conversion of the DICOM file between the Blue Sky Plan and R2GATE Windows.

(iii) Verification of the surgical guide model of the dental implant procedure using the STL file. The degree of bonding or precision measurement between the design file and the actual structure were reviewed and compared., The differences were within the acceptable range.

The test results met the acceptance criteria and demonstrated equivalence between the subject and predicate device.

9. Conclusion Regarding Substantial Equivalence

The R2GATE has similar indications for use and incorporate the same fundamental functions, views and module as the predicate device Blue Sky Bio Plan cleared under premarket notification K090607. The performance test for both the subject and the predicate device has been conducted and the test outcome support substantial equivalence between R2GATE and Blue Sky Bio Plan without raising any new issues of safety or effectiveness.