October 20, 2023

MegaGen Implant Co. Ltd
℅ Dave Kim
President
Mtech Group
7505 Fannin St, Suite 610
HOUSTON, TX 77054

Re: K223909
Trade/Device Name: R2GATE Lite ™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 4, 2023
Received: October 4, 2023

Dear Dave 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT 8B: Division of Radiological Imaging
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OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223909

Device Name
R2GATE Lite ™

Indications for Use *(Describe)*
R2GATE Lite ™ is intended for use as a pre-planning software for dental implant placement and surgical treatment for adult only.

R2GATE Lite ™ allows for surgical guides to be export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires FDA cleared or legally marketed 3D printing fabrication method and compatible material (biocompatible and sterilizable).

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

K223909

1. Submitter Information**:**

MegaGen Implant Co., Ltd
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Republic of Korea

Contact Person: Tae Gyoun Lee / Manager
Telephone Number: +82-53-222-3878

Date Prepared: 10/11/2023

2. Device Name:

Proprietary Name:	R2GATE Lite ™
Regulation Number	21 CFR §892.2050
Regulation Name:	Medical image management and processing system
Device Class:	Class II
Product Code:	LLZ

3. Predicate Device:

Trade/Device Name:	R2GATE
510k Number:	K190096
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical image management and processing system
Regulatory Class:	Class II
Product Code:	LLZ

4. Description of Device:

The proposed device, R2GATE Lite ™ software is an image viewer compatible for Windows PC, MacOS and Apple iOS tablet platform to view and approve pre-operative planning for dental implant placement and surgery provided by R2GATE Window (K190096).

The software R2GATE Lite ™ is used by dental professionals with clinical experience in implant surgery and in medical image review.

R2GATE Lite ™ let the user view, measure, zoom and rotate 2D and 3D images of dental implant plans generated by R2GATE Window (K190096). R2GATE Lite ™ can be used by dental professionals as a patient consultation tool for planning dental implant surgery and treatment.

R2GATE Lite ™ let the user review, revise and approve the implant surgical plan on Windows PC, MacOS and Apple iOS tablet platform before manufacturing a surgical guide.

5. Indications for Use:

R2GATE Lite ™ is intended for use as a pre-planning software for dental implant placement and surgical treatment for adult only.
R2GATE Lite ™ allows for surgical guides to be export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires FDA cleared or legally marketed 3D printing fabrication method and compatible material (biocompatible and sterilizable).

6. Substantial Equivalence:

Table 6-1 Substantial equivalence comparison table

Criteria	Predicate Devices	Device under Consideration	Equivalency
Element of Comparison	MegaGen Implant Co., Ltd,	MegaGen Implant Co., Ltd,	
Device Name	R2GATE Windows	R2GATE Lite ™	
510(k) Number	K190096	K223909	
Intended Use	Create, edit and review online implant plan case for approval.	Create, edit and review online implant plan case for approval.	Same
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.	R2GATE Lite ™ is intended for use as a pre-planning software for dental implant placement and surgical treatment for adult only. R2GATE Lite ™ allows for surgical guides to be export to a validated manufacturing center or to the point of care. Manufacturing at the point of care requires FDA cleared or legally marketed 3D printing fabrication method and compatible material (biocompatible and sterilizable).	reduced functionality
Media for Delivery	Download installation software file	Download installation software file	Same

Operating Platform	Software application for online Software application for desktop	Software application for online Software application for desktop Software application for mobile device	Difference
Program language	C# C++	C#	Same
Operating System	Windows PC	Windows PC, macOS, iOS	Different
software functionalities			
Nerve canal	The user can create a nerve canal model using the tools provided on the panoramic screen. The cross section of the model created is displayed in 2D and 3D volumetric view.	A 3D model of the nerve canal can be created using the information of the nerve canal model created in R2GATE Windows. The cross section of the created model is displayed in the 2D view and 3D volumetric view.	Same
3D model scan implant planning	A scanned 3D model (STL file) can be imported and used for implant treatment planning.	A 3D model (STL file) of mobile data created in R2GATE Window scan be imported and used for implant treatment planning.	Same
Image processing	The image displayed can be manipulated on the 2D or 3D screen with the tool provided by the program.	The image displayed can be manipulated on the 2D or 3D screen with the tool provided by the program.	Same
Measurement Tools	Angles and lengths can be measured on a 2D screen using tools provided by the program. Measure the length of two points and measure the angle using the slope of the two points.	Angles and lengths can be measured on a 2D screen using tools provided by the program. Measure the length of two points and measure the angle using the slope of the two points.	Same

Implant Control	Implant models can be added, deleted, moved and rotated on the screen. Different implant products are available to choose. The implant products can only be provided by the program.	Implant models can be added, deleted, moved and rotated on the screen. Different implant products are available to choose. The implant products can only be provided by the program.	Same
Anchor pin Control	Anchor-pin can be added, deleted, moved and rotated on the screen. Different Anchor-pin products that are only provided by the program are available to choose.	Anchor-pin can be added, deleted, moved and rotated on the screen. Different Anchor-pin products that are only provided by the program are available to choose.	Same
2D Image View	The imported CT data can be viewed in the form of axial, coronal, sagittal, cross section, and panorama image.	CT data of mobile data created in R2GATE Windows can be viewed in the form of axial, coronal, and sagittal image.	reduced functionality
View Management	2D/3D view can be enlarged / reduced, moved and rotated.	2D/3D view can be enlarged / reduced, moved and rotated.	Same
Project Management	The user can create a new project, save or load the existing project.	The user can proceed with the project already created in R2GATE Windows, save or load the existing project in R2GATE Windows.	reduced functionality

7. Analysis of differences

The proposed device has same indications for use and partly the same basic functionalities compared to the predicate device. The functions, view, and module for both the subject and predicate devices are used for review of radiographic images, creation of a dental treatment plan and implant surgical guide. The differences include that R2GATE Lite TM utilizes Windows PC, Apple MacOS, iOS tablet to review, revise and approve a pre-loaded implant image data generated by R2GATE Window (K190096) for an implant surgical simulation and treatment guide.

Both R2GATE Lite TM and R2GATE Windows can be downloaded to a local computer from the website allowing the dental professional flexible and convenient way to plan and review implant surgical guide.

8. 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. The comparison tests confirm the functionality, safety and efficacy of the proposed devices.

9. Conclusion Regarding Substantial Equivalence

The R2GATE Lite ™ has similar indications for use and incorporate the same fundamental functions, views and module as the predicate device R2GATE Windows cleared under premarket notification K190096. The performance test for both the subject and the predicate device has been conducted and the test outcome support substantial equivalence between R2GATE Lite ™ and R2GATE Windows without raising any new issues of safety or effectiveness.