April 4, 2022

Trate AG
℅ Jorge Millan
Regulatory Director
Sigma Biomedical
7737 N University Drive, Suite 101
Tamarac, Florida 33321

Re: K220022
Trade/Device Name: TRATE Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 21, 2021
Received: January 5, 2022

Dear Jorge Millan:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220022

Device Name
TRATE DENTAL IMPLANT SYSTEM

Indications for Use *(Describe)*
TRATE Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. TRATE Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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.

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510(K) Summary

Submitter Information

Submitter	TRATE AG Seestrasse 58 H-8806 Bäch (Switzerland) Phone: +41 44 202 1919 Fax: +41 44 202 1920
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Date prepared:	April 4, 2022

Subject Device Name

Trade/Proprietary Name:	TRATE Dental Implant System
Common or Usual Name:	Root-form Endosseous Dental Implants & Abutments
Regulation Number:	21 CFR 872.3640
Regulation Name:	Endosseous dental implants
Product Code:	DZE (Primary) NHA (Additional)
Class	II
Panel	Dental

Predicate Devices

Predicate Devices:	Primary Predicate: A.B. Dental Devices Ltd., K162482 Reference devices: A.B. Dental Devices Ltd., K132125

Device Description:

The TRATE Dental Implant System is an endosseous dental implant and abutment system consisting of screw-type implants manufactured of Titanium Alloy (Ti6AlV4, acc. to EN ISO 5832-3/ASTM F136). The implants are blasted with HAP / TCP for surface roughening, acid-etched and anodized. The cover screws, abutment fixation screws and abutments are made of Titanium Alloy (Ti6A14V). Some subject devices are surfaced anodized. TRATE Dental Implant System implants are two-piece implants:

TRATE Dental Implant System implant type is a two-component ROOTFORM implant with combined thread and tapered connection is intended for surgical placement in the upper or lower jaw to support crowns, bridges or overdentures in edentulous and partially edentulous jaws of patients in order to restore the patients chewing function, for single or multiple unit restorations. TRATE Dental Implant System implants are indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Implant model:

ROOTFORM Dental Implant
Diameters: 3.5 mm, 3.8 mm, 4.2 mm, 4.8 mm, 5.5 mm
For each diameter, available lengths: 8 mm, 10 mm, 12 mm, 14 mm, 16 mm

Abutment models:

Type of abutment	Diameter	Lengths
Gingiva formers (GFx, GFNx)	4 mm, 5 mm	0.5 mm - 7 mm
Anatomical straight (Ax, A1N)	3.98 mm, 4.8 mm	9.3 mm, 10.3 mm, 11.3 mm, 12.3 mm
Anatomical angled 15˚, 25˚ (AxAxx)	4.8 mm, 4.9 mm	9 mm, 10 mm, 11 mm, 12 mm
Multi-unit straight (Mx, MSx)	4 mm, 4.5 mm	1 mm, 2 mm, 3 mm, 4 mm
Multi-unit angled 15˚ (MxAxx)	4 mm	1 mm, 2 mm, 3 mm, 4 mm
Cover screws/Abutment fixation screws	One size only	One size only

Temporary Abutments

A gingiva former, called else as a healing cap or healing abutment that is screwed onto the top of the implant. Healing abutment placement is based on the surgical technique followed i.e., immediately placed during single stage surgical procedure or later at two-stage surgical protocol to guide the healing of soft tissue to replicate the contours and dimensions of natural tooth that is being replaced and to ensure access to the implant restorative platforms for impression and definitive abutment placement. In TRATE Dental Implant System available a few variations of gingiva formers: Regular gingiva formers and narrow gingiva formers.

Retained Abutments

An abutment is a component that is intermediate between the implant and the restoration and is retained to the implant by a screw. In TRATE system available are the following variations of abutments: Anatomical straight abutments (regular and narrow), anatomical angled abutments, multi-unit straight abutments (regular and narrow), multi-unit angled abutments.

Indications for Use:

TRATE Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. TRATE Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Non-Clinical Data:

In support of substantial equivalence safety and performance testing has been conducted to evaluate biocompatibility, bacterial endotoxin levels, sterility levels, total organic content. Mechanical performance in terms of dynamic compression-bending testing was performed to support substantial equivalence. Dynamic testing was performed on worst-case subject device constructs. Non-clinical product evaluation to demonstrate substantial equivalence includes:

- Dynamic fatigue testing according to ISO 14801
- Biocompatibility testing according to ISO 10993
- Surface analysis SEM & EDX-surface evaluation
- Bacterial endotoxin batch testing including Limulus amebocyte lysate (LAL) test will be conducted according to ANSI/AAMI ST72 on samples of water used in manufacturing on a bimonthly basis and on samples from sterilized product on a quarterly basis to demonstrate all sterile product meets a limit of< 20 EU/device.
- Implant sterilization validation was conducted on the implants according to ISO 11137-1, -2
- Abutment sterilization validation was conducted on the implants according to ISO 17665-1, -2
- Package integrity testing and accelerated aging were conducted according to ISO 11607
- Non-clinical worst-case MRI review was performed to evaluate the metallic TRATE Dental Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

Technological Characteristics Comparison

Device	TRATE Dental Implant System	A.B. Dental Devices Dental Implant System	A.B. Dental Devices Dental Implant System (Reference Device)
510K	K220022	K162482	K132125
Regulation Description	Endosseous Dental Implant	Endosseous Dental Implant	Endosseous Dental Implant
Class	Class II	Class II	Class II
Product Code	DZE	DZE	DZE
Regulation Number	872.3640	872.3640	872.3640

Indications for Use	TRATE Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. TRATE Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	A.B. Dental Devices -Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. Dental Devices Dental Implant System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. P4 and P14 abutments are to be used only with standard platform implants 3.5 mm diameter or larger	A.B. DENTAL DEVICES@ Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. A.B. DENTAL DEVICES@ Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Surgical Procedure Type	Single-Stage Two-Stage procedures	Single-Stage Two-Stage procedures	Single-Stage Two-Stage procedures

Implants		
510K	K220022	K162482
Raw Material	Ti6Al4V	Ti6Al4V
Surface Treatment	Blasted and acid etched	Blasted and acid etched
Implant / Abutment connection	Internal hex	Internal hex
Implant Body contour	Tapered and conical	Tapered and conical
Self-taping	Yes	Yes
Sterilization method	Gamma	Gamma
Packaging (Microbial Barrier)	Single sterile barrier (Tyvek-lidded blister)	Double Sterile barrier (Plastic container with a ca)
Diameters	Diameter 3.5 mm, 3.8 mm, 4.2 mm, 4.8 mm, 5.5 mm	Diameter: 3.5 mm, 3.75 mm, 4.2 mm, 4.5 mm, 5 mm, 6 mm

Lengths	Length: 8 mm, 10 mm, 12 mm, 14 mm, 16 mm for each of the implant diameters	Lengths: 8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm for each of the implant diameters
MRI Compatibility	MR Conditional	Unknown

TRATE implants are similar to the predicate implants with insignificant difference in:

- diameter. The wide diameter implants have more material than a standard diameter abutment. Therefore, TRATE Implants does not create a new, worst case.
- Material, manufacturing methods (including color anodization) and sterility are substantially equivalent between the subject and predicate device
- MR Conditional labeling was established by evaluating the system (including worst-case(s) of all variations of compatible implant bodies, dental abutments, and fixation screws) based on scientific rationale and published literature.
- Differences in sterile barrier packaging are addressed via labeling mitigations to ensure sterility is maintained during unpackaging.

Description	**Healing Caps (GFx, GFNx)**	**Healing Caps (P0)**
510K	K220022	K132125
Raw Material	Ti6Al4V	Ti6Al4V
Microbial state / Sterilization method	Non-sterile / steam	Non-sterile / steam
Platform	Narrow, Standard	Narrow, Standard
Diameter	4 mm, 5 mm	4 mm, 4.5 mm
Collar Length	0.5 mm - 7 mm	0.5 mm - 7 mm
Angle	No	No
Sterility	Non-sterile	Non-sterile

TRATE abutments are similar to the predicate abutments with insignificant difference in:

- diameter. The wide diameter abutment has more material than a standard diameter abutment. Therefore, this abutment does not create a new, worst case.
- Material, manufacturing methods (including color anodization) and sterility are substantial equivalent between the subject and predicate device

Description	**Abutments anatomic straight (Ax, A1N)**	**Abutments straight (P3)**
510K	K220022	K132125
Raw Material	Ti6Al4V	Ti6Al4V
Microbial state / Sterilization method	Non-sterile / steam	Non-sterile / steam
Collar length (mm)	1 mm, 2 mm, 3 mm, 4 mm	1 mm, 2 mm, 3 mm

Platform	Narrow, Standard	Narrow, Standard
Diameter	3.98 mm, 4.8 mm	3.75 mm, 4.5 mm, 5 mm, 5.5 mm
Length	9.3 mm, 10.3 mm, 11.3 mm, 12.3 mm	5 mm, 7 mm, 9 mm, 11 mm, 12 mm, 15 mm
Angle	No	No
Cement Retained	Yes	Yes
Sterility	Non-sterile	Non-sterile

TRATE abutments are similar to the predicate abutments with insignificant difference in:

- diameter. The subject device abutment has a bigger smallest diameter than a predicate abutment. Therefore, this abutment does not create a new, worst case.
- collar length. The addition of an additional collar length does not create a new worst-case for straight abutments
- length. Length of subject device in between the range of predicate device and this is not create a new worst-case
- Material, manufacturing methods (including color anodization) and sterility are substantial equivalent between the subject and predicate device

Description	**Abutments anatomic angled (AxAxx)**	**Abutments anatomic angled (P4)**
510K	K220022	K162482
Raw Material	Ti6Al4V	Ti6Al4V
Microbial state / Sterilization method	Non-sterile / steam	Non-sterile / steam
Collar length (mm)	1 mm, 2 mm, 3 mm, 4 mm	1 mm, 2 mm, 3 mm
Platform	Standard	Narrow, Standard
Diameter	4.8 mm, 4.9 mm	4,7 mm, 5 mmm
Length	9 mm, 10 mm, 11 mm, 12 mm	9 mm, 10 mm, 10.75 mm, 11 mm, 12 mm
Angle	15˚, 25˚	15˚, 25˚
Cement Retained	Yes	Yes
Sterility	Non-sterile	Non-sterile

TRATE abutments are similar to the predicate abutments with insignificant difference in:

- collar length. Adding longer collar length is addressed through bench testing (ISO 14801). Thus, established compatibility limitations to the angled abutments (MxAxx and AxAxx abutments are to be used only with implants 3.5 mm diameter or larger and only for multiple unit restorations).
- diameter. because predicate device have smaller diameter, subject devices does not create a new worst-case
- Material, manufacturing methods (including color anodization), and sterility are substantial equivalent between the subject and predicate device

Description	Multi-unit abutments straight (Mx, MSx)	Straight adaptor (P16)
510K	K220022	K132125
Raw Material	Ti6Al4V	Ti6Al4V
Microbial state / Sterilization method	Non-sterile / steam	Non-sterile / steam
Collar length (mm)	1 mm, 2 mm, 3 mm, 4 mm	1 mm, 2 mm, 3 mm, 4 mm, 5 mm
Platform	Narrow, Standard	Narrow, Standard
Diameter	4 mm, 4.5 mm	4 mm, 4.5 mm
Angle	No	No
Cement Retained	Yes	Yes
Sterility	Non-sterile	Non-sterile

The two abutments have the same design, and differ only in one additional length available in the subject predicate. Material, manufacturing methods, and sterility are substantial equivalent between the subject and predicate device

Description	Multi-unit abutments angled (MxAxx)	Multi-unit Angular Adaptor (P14)
510K	K220022	K132125
Raw Material	Ti6Al4V	Ti6Al4V
Microbial state / Sterilization method	Non-sterile / steam	Non-sterile / steam
Collar length (mm)	1 mm, 2 mm, 3 mm, 4 mm	1 mm, 3 mm
Platform	Standard	Standard
Diameter	4 mm	4 mm
Angle	15˚	17˚, 30˚
Cement Retained	No	No

Screw Retained	Yes	Yes
Sterility	Non-sterile	Non-sterile

TRATE abutments are similar to the predicate abutments with insignificant difference in:

- angle. An engineering rationale shows that the angulation of the subject abutment is less than predicate, resulting in a shorter moment arm. Further, the wide diameter abutment has more material than a standard diameter abutment. Therefore, this abutment does not create a new, worst case.
- collar length. Adding longer collar length is addressed through bench testing (ISO 14801). Thus, established compatibility limitations to the angled abutments (MxAxx and AxAxx abutments are to be used only with implants 3.5 mm diameter or larger and only for multiple unit restorations).
- Material, manufacturing methods (including anodization), and sterility are substantial equivalent between the subject and predicate device

Similarities: Indications for Use

All devices are intended for surgical restorative applications for placement in the bone of the upper and lower jaw, to provide support for prosthetic devices, such as artificial teeth. Intended Use, intended and indications, and clinical application differ slightly in wording, but are fully equivalent on content level.

Technological Similarities:

All systems presented make use of the very same basic design consisting of full body, threaded, Titanium implants and abutments. All predicate devices (implants) are surface-treated to increase bone-implant contact, and hence facilitate osteointegration. All three use Gamma radiation to sterilize their implants. TRATE Dental Implant System Abutments are similar in design, technological characteristics and encompass dimensions as predicate abutments. No technological differences exist in materials, manufacturing technology, design or intended use. To improve the restorative process all systems offer angulated abutments. All abutments are provided non-sterile to the end-user in a single-unit package, and are for single patient, single-use only. Mechanical testing results demonstrate similar maximum loads.

Differences

When comparing the TRATE Dental Implant System implants and abutments to similar cleared devices there are no technological, design or material differences. Indications for use are similar. The differences are in the dimensions of the subject devices which are within the range of predicate devices. The sterile barrier implant body packaging is also different than the predicate packaging but this difference is mitigated in the labeling, A labeling difference between the TRATE Dental Implant System and the predicate device is that TRATE Dental Implant System is labeled as MR Conditional, which is addressed through scientific rationale and published literature evaluating the worst-case of the subject system. Due to the difference in sterile-barrier packaging, labeling differences also include handling for single-sterile barrier packaging.

Conclusion:

ROOTFORM Dental Implants and its predicate devices have the similar intended use, have similar technological characteristics, and are made of similar materials and surface treatments. All devices encompass the same range of physical dimensions, including diameter and length of

the implants, diameter and angulation of the abutments, and the materials and designs of abutments. All devices are packaged in similar materials and sterilized using similar methods.