



October 3, 2019

Alfa Gate Mazen Ltd
% Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22815 Ventura Blvd
Woodland Hills, California 91364

Re: K182143

Trade/Device Name: ALFA GATE® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 9, 2019
Received: July 9, 2019

Dear Daniela Levy:

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 Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

**SECTION 4 -****Indication for Use Statement**

510(k) Number (if known):

K182143

Device Name:

ALFA GATE® Dental Implants System

Indications for Use (*Describe*)

Indications for Use:

ALFA GATE® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. ALFA GATE® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. ALFA GATE® 3.0Ømm S-LINE & SLIM implants are intended for placement at the mandibular central and lateral incisors and maxillary lateral incisors. Indicated also for denture stabilization using multiple implants. Two Stage Implants: M+, S-LINE, SCI, SCIP, MAX. One Stage Implants: SLIM Implants.

ALFA GATE Dental Implants longer than 13mm are to be used with straight abutments only.

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

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)



SECTION 5 - 510(k) Summary (21 CFR 807.92)

510(k) Number K182143

- 1 Type of Submission Premarket Notification (21 CFR 807.90(e)) 510(k) Traditional
- 2 Submission Owner ALFA GATE MAZEN LTD.
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- 3 Official Correspondent Sterling Medical Registration
Contact Person Daniela Levy - Regulatory Consultant
22815 Ventura blvd.
Woodland Hills, CA 91364
Phone: 1-213-787-3027
Email: sterlingmedical2017@gmail.com;
daniela@sterlingmedicalregistration.com
- 4 Date Prepared October 3rd , 2019
- 5 Device Trade Name ALFA GATE® Dental Implants System
- 6 Regulation Description Endosseous Dental Implants
- 7 Classification

Product Code	:	DZE
Device Name	:	Implant, endosseous, root-form
Regulation No	:	872.3640
Class	:	II
Panel	:	Dental
Secondary Product Code: NHA		
- 8 Reason for the Premarket Notification Submission : New Device
- 9 Identification of Legally Marketed Predicate Devices:
Primary Predicate:
SGS International ltd - SGS Dental Implants System K182219;



Reference Devices:

SGS International Ltd - SGS Dental Implants System K133362;

10 Device Description: :

ALFA GATE® Dental Implant System is consist of endosseous form Dental Implants, Internal hex Implants, Internal Conical Connection Implants, One piece Implants, tapered design; cover screws, healing caps and abutment systems; Dental Implants are provided in two options of surface treatment (1) Bioactive Surface-CaP which is a calcium phosphate coating; or (2) Sand blast large particles with acid etched;

Dental Implants:

M+ IMPLANTS - Internal Hex, Conical Connection Implant

Measurements: Diameter mm 3.5, 4.3, 5.0, 6.0; with Length mm 8, 10, 11.5, 13, 16(not for 6Ø mm);

S-LINE Implants - Internal Hex implant, Narrow Implants

BIOACTIVE S-LINE Implant - Measurements: Diameter mm 3.0 with Length mm 10, 11.5, 13;

POROUS S-LINE Implant - Measurements: Diameter mm 3.0 with Length mm 10, 11.5, 13;

SCI Implants - Internal Hex implant, Spiral conical design

BIOACTIVE SCI Implant - Measurements: Diameter mm 3.3, 3.75, 4.2, 4.7, 5.2, 6.0 with Length mm 8, 10, 11.5, 13, 16 (not for 5.2Ø,6Ø mm);

POROUS SCIP Implant - Measurements: Diameter mm 3.3, 3.75, 4.2, 4.7, 5.2, 6.0 with Length mm 8, 10, 11.5, 13, 16 (not for 5.2Ø,6Ø mm);

MAX Implant - Internal hex implant, cylindrical and conical body design

Measurements: Diameter mm 3.3, 3.75, 4.2, 4.7, 5.2 with Length mm 8, 10, 11.5, 13, 16;

SLIM Implant - One Piece implants

Measurements: Diameter mm 3.0, 3.3, 3.75 with Length mm 10, 11.5, 13, 15;

Dental Abutments:

Straight abutments (Regular, Thin, Wide, Narrow), Angled Abutments 15° (Regular, Short), Multi Unit, Shoulder abutments, Esthetic Abutments, Concave Esthetic Abutments, Esthetic Abutments 15°, Concave Angulated Abutments 15°, Esthetic Abutments , Alfa lock abutment (locator), Ball attachment Abutment, Ball attachment



concave, Healing Caps (Narrow, Regular, Wide, Slim), Concave healing caps, Anatomic Abutment. Angled abutments are only to be used with S-Line, SCI, and MAX implants. M+ and SLIM implants are not to be used with angled abutments.

Dental Abutments Conical Connection:

Anatomic straight Abutment (RP, NP), Standard straight abutment (RP, NP), Ball attachment (RP, NP), Healing Caps (RP, NP).

11 Indication for Use :

ALFA GATE® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. ALFA GATE® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. ALFA GATE® 3.0Ømm S-LINE & SLIM implants are intended for placement at the mandibular central and lateral incisors and maxillary lateral incisors. Indicated also for denture stabilization using multiple implants. Two Stage Implants: M+, S-LINE, SCI, SCIP, MAX. One Stage Implants: SLIM Implants.

ALFA GATE Dental Implants longer than 13mm are to be used with straight abutments only.

12 Performance Standards or Guidance Documents :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- ISO 11137-1:2006 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11737-2: 2009 Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ASTM F-1980 - 16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices



- ISO 17665-1:2006 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-2:2009 Sterilization of health care products -- Moist heat -- Part 2: Guidance on the application of ISO 17665-1
- ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff
- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.
- Chemical and SEM analysis performed on implants per Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.
- Endotoxin batch testing protocol per FDA Guidance Document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff



13 Substantial Equivalence

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SE Table - Indication for Use:

	<i>Candidate</i>	<i>Primary Predicate</i>	<i>Reference Device</i>
	ALFA GATE	SGS International	SGS International
K Number	K182143	K182219	K133362
Indication for use	ALFA GATE® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. ALFA GATE® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. ALFA GATE® 3.0Ømm S-LINE & SLIM implants are intended for placement at the mandibular central and lateral incisors and maxillary lateral incisors. Indicated also for denture stabilization using multiple implants. Two Stage Implants: M+, S-LINE, SCI, SCIP, MAX. One Stage Implants: SLIM Implants. ALFA GATE Dental Implants longer than 13mm are to be used with straight abutments only.	SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. Narrow diameter implants (3.2) are intended for maxillary lateral incisors and mandibular lateral and central incisors. Two Stage Implants: P7N, P1D, P5D, P7D. PEEK Temporary Abutments are not to exceed 30 days.	SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: P1, P7, P7N. One Stage: P7S, P9S. One Stage & One-Piece 3.0 mm diameter implants: P7S, P9S are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. One stage & One-Piece 2.4 mm diameter implants for temporary use or long term use: P9S permit immediate splint stability and long term fixation of new or existing crown, bridge and prosthesis, and protection of graft sites. PEEK Temporary Abutments are not to exceed 30 days.

SE – Indication for Use Discussion -

The candidate ALFA GATE SLIM share the same indication for use as its primary predicate SGS K182219 and reference device SGS K133362. Minor differences are that SGS K133362 introduces smaller onepiece implants and narrow implants with 2.4Ø, where ALFA GATE introduces the SLIM onepiece implants and S-LINE narrow implants with 3.0Ø. However still sharing the same indication and therefore, ALFA GATE can be considered to be substantially equivalent to its reference device.



SE - Dental Implants

Characteristic	Candidate M+ Implants (Cat# SCA)	Primary Predicate P7D - Dental Implant with Double Connection
510(k) number	K182143	K182219
Manufacturer	Alfa Gate Mazen Ltd	SGS International Ltd
Product Name	M+ Implants	P7D - Dental Implant with Double Connection
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements mm	3.5 Ø: 8, 10, 11.5, 13, 16 4.3 Ø: 8, 10, 11.5, 13, 16 5.0 Ø: 8, 10, 11.5, 13, 16 6.0 Ø: 8, 10, 11.5, 13	3.5Ø : 8, 10, 11.5, 13, 16 3.75Ø: 8, 10, 11.5, 13, 16 4.2Ø : 8, 10, 11.5, 13, 16 4.5Ø : 8, 10, 11.5, 13, 16 5.0Ø: 8, 10, 11.5, 13, 16 6.0Ø: 8, 10, 11.5, 13, 16
Connection Type	Internal hex conical connection, cone angulation 23.5°	Internal hex conical connection , cone angulation 18°
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Sand Blast and acid-etched	Calcium Phosphate Coating
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

SE Discussion

Technical Parameters comparison:

The candidate ALFA GATE M+ Implants share the same implant design, raw materials and implants' measurements as its primary predicate SGS K182219. The differences are related to the cone angulation, diameter and surface treatment. ALFA GATE cone angulation is 23.5°, Primary Predicate SGS cone angulation is 18°. This is considered to be minor difference as verified by Fatigue Test results. ALFA GATE introduces 4.3Ø where the primary predicate SGS K182219 introduces 4.2Ø however this is considered to be minor differences as this is covered by the range of the primary predicate SGS K182219. The implant surface is Sand Blasted and acid-etched, which is demonstrated as substantially equivalent per recommendations of the FDA Class II Special Controls Guidance Document *Root-form Endosseous Dental Implants and Endosseous Dental Abutments*. Therefore ALFA GATE M+ Implants can be considered substantially equivalent to its primary predicate SGS K182219.

Characteristic	Candidate BIOACTIVE S-LINE Implant (Cat# S-LINE)	Candidate POROUS S-LINE Implant (Cat# S-	Reference Device SGS P7N Narrow Conical Implant
510(k)number	K182143	K182143	K133362
Manufacturer	Alfa Gate Mazen Ltd	Alfa Gate Mazen Ltd	SGS International Ltd
Product Name	BIOACTIVE S-LINE Implant	POROUS S-LINE Implant	P7N Narrow Conical Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread	Tapered, Double Thread
Measurements mm	3.0 Ø: 10, 11.5, 13	3.0 Ø: 10, 11.5, 13	3.0 Ø: 10, 11.5, 13, 16 3.2 Ø: 10, 11.5, 13, 16
Connection	Internal Hex	Internal Hex	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate Coating	Sandblasted and acid etched	Calcium Phosphate Coating
Self tapping	✓	✓	✓
Sterilization	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging	Double packaging

SE Discussion

Technical Parameters comparison:

The candidate ALFA GATE BIOACTIVE S-LINE & POROUS S-LINE Implants share the same implant design, raw materials and implants' measurements as its reference device SGS K133362. Minor difference is related to implant surface, ALFA GATE BIOACTIVE S-LINE Implant is provided with surface treatment of Calcium Phosphate & HA as in similar to its reference device. Where the ALFA GATE POROUS S-LINE is provided with surface treatment of Sand Blast and acid etched, which is demonstrated as substantially equivalent per recommendations of the FDA Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutments. Therefore, ALFA GATE BIOACTIVE S-LINE & POROUS S-LINE Implants can be considered substantially equivalent to its reference device SGS K133362.

Characteristic	Candidate BIOACTIVE SCI Implant (Cat# SCI)	Candidate POROUS SCIP Implant (Cat# SCIP)	Reference Device SGS P1 Screw Type Groovy Implant
510(k)number	K182143	K182143	K133362
Manufacturer	Alfa Gate Mazen Ltd	Alfa Gate Mazen Ltd	SGS International Ltd
Product Name	BIOACTIVE SCI Implant	POROUS SCIP Implant	P1 Screw Type Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double	Tapered, Double Thread
Measurements mm	3.3 Ø: 8, 10, 11.5, 13, 16 3.75 Ø: 8, 10, 11.5, 13, 16 4.2 Ø: 8, 10, 11.5, 13, 16 4.7 Ø: 8, 10, 11.5, 13, 16 5.2 Ø: 8, 10, 11.5, 13 6.0 Ø: 8, 10, 11.5, 13	3.3 Ø: 8, 10, 11.5, 13, 16 3.75 Ø: 8, 10, 11.5, 13, 16 4.2 Ø: 8, 10, 11.5, 13, 16 4.7 Ø: 8, 10, 11.5, 13, 16 5.2 Ø: 8, 10, 11.5, 13 6.0 Ø: 8, 10, 11.5, 13	3.2 Ø: 8, 10, 11.5, 13, 16 3.75 Ø: 8, 10, 11.5, 13, 16 4.2 Ø: 8, 10, 11.5, 13, 16 4.5 Ø: 8, 10, 11.5, 13, 16 5.0 Ø: 8, 10, 11.5, 13, 16 6.0 Ø: 8, 10, 11.5, 13, 16
Connection	Internal Hex	Internal Hex	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface Treatment	Calcium Phosphate Coating	Sandblasted and acid etched	Calcium Phosphate Coating
Self tapping	✓	✓	✓
Sterilization	Gamma Ray	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging	Double packaging

SE Discussion

Technical Parameters comparison:

The candidate ALFA GATE BIOACTIVE SCI & POROUS SCIP Implants share the same implant design, raw materials and implants' measurements as its reference device SGS K133362. Minor difference is related to implant surface, ALFA GATE BIOACTIVE SCI Implant is provided with surface treatment of Calcium Phosphate & HA as in similar to its reference device. Where the ALFA GATE POROUS SCIP is provided with surface treatment of Sand Blast and acid etched, which is demonstrated as substantially equivalent per recommendations of the FDA Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutments. Therefore, ALFA GATE BIOACTIVE SCI & POROUS SCIP Implants can be considered substantially equivalent to its reference device SGS K133362.

Characteristic	Candidate MAX Dental Implants (Cat# MAX)	Reference Device SGS P1 Screw Type Groovy Implant
510(k) number	K182143	K133362
Manufacturer	Alfa Gate Mazen Ltd	SGS International Ltd
Product Name	MAX Implants	P1 Screw Type Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements mm	3.3 Ø: 8, 10, 11.5, 13, 16 3.75 Ø: 8, 10, 11.5, 13, 16 4.2 Ø: 8, 10, 11.5, 13, 16 4.7 Ø: 8, 10, 11.5, 13, 16 5.2 Ø: 8, 10, 11.5, 13	3.2 Ø: 8, 10, 11.5, 13, 16 3.75 Ø: 8, 10, 11.5, 13, 16 4.2 Ø: 8, 10, 11.5, 13, 16 4.5 Ø: 8, 10, 11.5, 13, 16 5.0 Ø: 8, 10, 11.5, 13, 16 6.0 Ø: 8, 10, 11.5, 13, 16
Connection	Internal hex	Internal Hex
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface	Sand Blast and acid-etched	Calcium Phosphate Coating
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

SE Discussion

Technical Parameters comparison:

The candidate ALFA GATE MAX Implants share the same implant design, raw materials and implants' measurements as its reference device SGS K133362. Minor difference is related to implant surface, the ALFA GATE MAX implant is provided with surface treatment of Sand Blast and acid etched, which is demonstrated as substantially equivalent per recommendations of the FDA Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutments. Therefore, ALFA GATE MAX Implants can be considered substantially equivalent to its reference device SGS K133362.

Characteristic	Candidate SLIM Implants (Cat# SCA)	Reference Device SGS P7S Integral Groovy Implant
510(k) number	K182143	K133362
Manufacturer	Alfa Gate Mazen Ltd	SGS International Ltd
Product Name	SLIM Implants	P7S Integral Groovy Implant
Thread Design	Tapered, Double Thread	Tapered, Double Thread
Measurements mm	3.0 Ø: 10, 11.5, 13, 15 3.3 Ø: 10, 11.5, 13, 15 3.75 Ø: 10, 11.5, 13, 15	3.0 Ø: 10, 11.5, 13, 16 3.2 Ø: 10, 11.5, 13, 16 3.75 Ø: 10, 11.5, 13, 16 4.2 Ø: 10, 11.5, 13, 16 5.0 Ø: 10, 11.5, 13, 16 6.0 Ø: 10, 11.5, 13, 16
Connection	One piece implant	One piece implant
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Surface	Calcium Phosphate Coating	Calcium Phosphate Coating
Self tapping	✓	✓
Sterilization	Gamma Ray	Gamma Ray
Packaging	Double packaging	Double packaging

SE Discussion

Technical Parameters comparison:

The candidate ALFA GATE SLIM Implants share the same implant design, raw materials, implants' measurements and surface treatment as its reference device SGS K133362. Therefore, ALFA GATE SLIM Implants can be considered substantially equivalent to its reference device SGS K133362.

SE - Dental Abutments:
Internal Hex

	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Straight abutment Cat#AGM-101 Straight abutment Cat#AGM-101H	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	Regular (RP), Length: 10.2	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	15° Abutment Cat#AGM-102	Angular Titanium Abutment,S2N,S2L, S2A
Dimensions mm	Regular (RP), Length: 9.5 - Angle 15	Narrow: Angle 15°, - length 9 mm Normal: Angle 15°, 25°- Length 9, 11 mm Normal: Height 1,2, 3 Length 9, 11
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Thin abutment Cat#AGM-104 Wide abutment Cat#AGM-110	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	Thin , Length: 10 Wide , Length: 11.5	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained

	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	High base Abutment Cat#AGM-108	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RN , Length: 13.5 mm ,	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Long neck Abutment Cat#AGM-109	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RN , Length: 14.5 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Angulated abutment 15° S-Line Cat#AGM-115S	Angular Abutments S2D, S2S, S2DS
Dimensions mm	NP, Length: 11 - Angle 15	NP,SLIM Length :11 - Angle 15, ,25
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	S-Line straight abutment Cat# AGM-	S-Lock Abutments S35N, S35D,S35,

	100S	
Dimensions mm	NP , Length: 10 mm	Narrow Diameter:3.0 Height: 1, 2, 3; Regular Diameter: 3.75 Height: 1,2, 3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Cementing post wide short Cat# AGM-104S	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	NP , Length: 7 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Multi unit straight abutment Cat# AGM-505 Titanium Sleeve	S16 The straight one-piece Multi-unit Abutment
Dimensions mm	NP , Length: 7 mm	RP , Height: 1,2,3,4,5 mm Related accessories: H-S16/S17 healing cap, T-S16/S17 Titanium sleeve, TW-S16/S17 Titanium sleeve, T3- S16/S17 adaptor
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained	Screw Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Metal housing Cat# AGM-105-M	Metal cap (S8-Metal Cap)
Dimensions mm	RP	RP
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Attachment Retained / Overdenture	Attachment Retained / Overdenture

	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Shoulder Abutment Cat#AGM-602- X	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RP , Height 1,2,3,4 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Esthetic Abutment Cat#AGM-802- X	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RP , Height 1,2,3,4 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Concave Esthetic Abutment Cat#AGM-802- XC	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RP , Height 1,2,3,4 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained

	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Standard short Abutment Cat# AGM-101S Wide short Abutment Cat# AGM-110S	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	RP , Length: 8 mm Wide, Length: 7.5 mm	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	15° short Abutment Cat# AGM-102S	Angular Titanium Abutment,S2N,S2L, S2A
Dimensions mm	Regular (RP), Length: 7 - Angle 15	Narrow: Angle 15°, - length 9 mm Normal: Angle 15°, 25°- Length 9, 11 mm Normal: Height 1,2, 3 Length 9, 11
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Cement Retained	Cement Retained
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	15° Thin Abutment Cat# AGM-102T	Angular Titanium Abutment,S2N,S2L, S2A
Dimensions mm	RP, Length: 11 - Angle 15	Narrow: Angle 15°, - length 9 mm Normal: Angle 15°, 25°- Length 9, 11 mm Normal: Height 1,2, 3 Length 9, 11
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	15° Esthetic Abutment Cat# AGM-102-Ex Concave Angulated Abutment 15° Cat# AGM-102-ExC	Angular Titanium Abutment,S2N, S2AN, S2AD,S2LD

Dimensions mm	RP, Height 1,2,3,4 - Angle 15	Narrow: Angle 25° - length 9 mm Narrow Anatomic: Angle 15°,25° - Height 1,2 mm Regular Anatomic: 3.75mm, Angle 15°,25° - Height 1,2,3,4 Regular: 3.75mm, Length 13mm, Angle 15°,25°
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex/conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Alfa lock abutment Cat# AGM-106-x	S35N, S35D,S35, S-Lock Abutments
Dimensions mm	RP, Height 2,3,4,5	Narrow Diameter:3.0 Height: 1, 2, 3; Regular Diameter: 3.75 Height: 1,2, 3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex/conical
Restoration	Screw Retained Overdenture	Screw Retained Overdenture
Related accessories	Metal housing Alfa gate Cat# AGM-106-M Plastic caps	Silicon caps: soft, standard, strong; Metal cap (MM-LFA50)
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	Ball Abutment Cat# AGM-105-x	Overdenture Ball attachment S3N, S3
Dimensions mm	RP, Heights 1,2,3,4,5,6,7 mm	Narrow: Length:1,2,3,4 Normal: Length:1,2,3,4,5,6,7
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained Overdenture	Screw Retained Overdenture
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	Ball Abutment Concave Cat# AGM-105-xC	Overdenture Ball attachment S3N, S3
Dimensions mm	RP, Heights 1,2,3,4,5 mm	Narrow: Length:1,2,3,4 Normal: Length:1,2,3,4,5,6,7
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained Overdenture	Screw Retained Overdenture
	Candidate	Reference Device

	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	Ball Abutment S-Line Cat# AGM-105-xS	Overdenture Ball attachment S3N, S3
Dimensions mm	NP, Heights 2,3,4,5 mm	Narrow: Length:1,2,3,4 Normal: Length:1,2,3,4,5,6,7
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained Overdenture	Screw Retained Overdenture
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International
K Number	K182143	K133362
Product Name	Healing cap Cat# AGM203-x Wide Healing cap Cat# AGM-203-xW Healing cap S-LINE Cat# AGM-203-xS Concave Healing cap Cat# AGM-203-xC	Healing Abutments (HN,HNN,HWN,H,HN, HW)
Dimensions mm	RP, WP, Heights 1,2,3,4,5,6,7 mm NP, Heights 2,3,4,5 mm Concave : RP, WP, Heights 1,2,3,4,5 mm	Narrow, Length: 2,3,4 Normal, Length: 2,3,4,5,6 Wide, Length: 3,5
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained Overdenture	Screw Retained Overdenture
	Candidate	Reference Device
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Anatomic Abutment Cat# AGM-207-xF	S16 The straight one-piece Multi-unit Abutment
Dimensions mm	Straight RP , Height: 1,2,3,4,5 mm Anatomic sleeve AGM-207-PF (plastic burn cap) Multi unit straight abutment Cat# AGM-505 (=metal sleeve)	Straight RP , Height: 1,2,3,4,5 mm Related accessories: H-S16/S17 healing cap, T-S16/S17 Titanium sleeve, TW-S16/S17 Titanium sleeve, T3-S16/S17 adaptor
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Hex	Internal Hex
Restoration	Screw Retained	Screw Retained

Conical Connection

	Candidate	Predicate
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number		K182219
Product Name	Anatomic straight Abutment (Cat# ASAC)	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	Narrow (NP), Height: 1,2,3,4 Regular (RP), Height: 1,2,3,4	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Conical Connection	Internal conical
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Standard straight abutment (Cat# SSAC)	Straight Titanium Abutment S1WN,S1D, S1ND, S1WD, S1W, S1W8D, S1W8
Dimensions mm	Narrow (NP), Length: 9, 13 Regular (RP), Length: 9, 13	Narrow: Wide - Length:9 Normal: Length: 7, 9, 12, 15 Narrow: Length: 7, 9 Wide: Length:9, 12 S1W8D, S1W8 - 8mm wide with 10mm length
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Conical Connection	Internal Conical Connection
Restoration	Cement Retained	Cement Retained
	Candidate	Primary Predicate
	Alfa Gate Mazen Ltd	SGS International Ltd
K Number	K182143	K182219
Product Name	Ball attachment (Cat# BAC)	Overdenture Ball Attachments P7N (K133362) WPKxx, S3D - Ball Attachment
Dimensions mm	Narrow (NP), Height: 1,2,3,4,5,6 Regular (RP), Height: 1,2,3,4,5,6	Narrow: NP, Height: 1,2,3,4; (K133362) int. hex Regular (RP), Height: 1,2,3,4,5,6
Material	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
Connection	Internal Conical Connection	Internal Conical Connection
Restoration	Overdenture	Overdenture
	Candidate	Primary Predicate



	Alfa Gate Mazen Ltd	SGS International Ltd
<i>K Number</i>	K182143	K182219
<i>Product Name</i>	Healing Cap (Cat# HCC xxx)	Healing Abutments (HD,HND,HW7D,HW8D,HWD)
<i>Dimensions mm</i>	Narrow (NP), Height: 2,3,4,5,6,7 Regular (RP), Height: 2,3,4,5,6,7	Narrow, Length: wide 2,3,4; Normal, Length: 2,3,4,5,6 Wide, Length: 3,5
<i>Material</i>	Titanium alloy Ti-6Al-4V-ELI.	Titanium alloy Ti-6Al-4V-ELI.
<i>Connection</i>	Internal Conical Connection	Internal Conical Connection

14 Summary of Equivalence:

As in similar to its primary predicate and reference devices ALFA GATE Dental Implants and Dental Abutments are Class II.

As in similar to its primary predicate and reference devices ALFA GATE Dental Implants are provided sterile by Gamma Ray irradiation; Dental Abutments are provided non sterile and prior to their use must be sterilized in an autoclave.

As in similar to its primary predicate and reference devices ALFA GATE Dental Implants and Abutments are for Single Use only.

SE discussion

The raised differences raised by the substantial equivalent tables and SE discussion are considered to be minor, e.g. abutments measurements which are covered by the range of primary predicate and referenced devices and/or very similar to them. The compatibility of implant/abutment was also verified by performance testing and therefore the candidate ALFA GATE® can be considered substantial equivalent to its primary predicate and reference devices.

15 Performance Testing:

Clinical Testing - No clinical data is included in this submission.

Sterilization Validation Test was carried out with accordance to ISO 11137 in order to demonstrate the substantial equivalence related to ALFA GATE® Dental Implants - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Shelf Life Test was carried out with accordance to ASTM F-1980 in order to validate the claimed shelf life of 5 years.



Steam Sterilization Test was carried out with accordance to ISO 17665 in order to demonstrate the substantial equivalence related to ALFA GATE® Dental Abutments - Test results have demonstrated that the SAL of 10^{-6} was achieved and all testing requirements were met.

Endotoxin batch testing protocol per FDA Guidance Document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.

Biocompatibility - ALFA GATE Dental Implants are made of Ti6Al4V ELI using the conventional manufacturing process. Cytotoxicity testing was carried out with accordance to ISO 10993-5 in order to demonstrate that the manufacturing process did not change the biocompatibility profile. Sensitization testing was carried out with accordance to ISO 10993-10. No additional biocompatibility testing was deemed necessary since the devices are constructed from medical quality raw material intended for surgical implants applications.

Fatigue test was carried out with accordance to ISO 14801 in order to verify the mechanical connection strength of implant/abutment, results have demonstrated the performance with the use of ALFA GATE® Dental Implants / Abutments.

Surface Test was carried out to ensure the cleanness of the implant surface, surface results were met ALFA GATE requirements.

Risk Assessment was carried out with accordance to ISO 14971 and has demonstrated no new safety and/or effectiveness issues.

16 Conclusion:

As verified by substantial equivalence, risk assessment and bench testing ALFA GATE® Dental Implants System shares similarity to its predicated devices in terms of intended use, indication for use, raw material, technological characteristics and performance. Therefore, ALFA GATE® Dental Implants system is considered to be substantially equivalent to its predicate devices.