March 21, 2025

Prismatik Dentalcraft, Inc.
Haiyan Wei
Principal Regulatory Affairs Specialist
2144 Michelson Drive
Irvine, California 92612

Re: K242564
Trade/Device Name: Autoclavable Cassette (Glidewell HT™ Implant Guided Surgical Kit, Glidewell HT™ Implant Surgical Kit, Glidewell™ Prosthetic Kit)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 18, 2025
Received: February 18, 2025

Dear Haiyan Wei:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.03.21 14:49:15 -04'00'

for: Christopher K. Dugard, M.S.
Division Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242564

Device Name
Autoclavable Cassette (Glidewell HT™ Implant Guided Surgical Kit, Glidewell HT™ Implant Surgical Kit, Glidewell™ Prosthetic Kit)

Indications for Use *(Describe)*
The Autoclavable Cassettes are used in healthcare facilities to organize surgical and prosthetic instruments during sterilization, storage, and transport during and after surgical uses. The Autoclavable Cassettes are not intended to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated sterilization wrap to maintain the sterility of the enclosed devices.

Sterilization parameters:
Pre-vacuum steam: 132°C (270° F) for 4 minutes with 30 minutes drying time.

Sterilization validations for the worst-case Autoclavable Cassette included cassette and instruments. The Autoclavable Cassettes are validated for a maximum load of 641 grams for Glidewell HT™ Implant Guided Surgical Kit, 476 grams for Glidewell HT™ Implant Surgical Kit, and 192 grams for Glidewell™ Prosthetic Kit.

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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PRISMATIK DENTALCRAFT, INC.

510(k) Summary
K242564

Submission Date: February 18, 2025

I. Contact Details

Applicant Name: Prismatik Dentalcraft, Inc.

Address: 2144 Michelson Drive, Irvine, CA 92612 United States

Applicant Contact: Ms. Haiyan Wei, Principal Regulatory Affairs Specialist

Email: Haiyan.Wei@glidewelldental.com

Phone: 949-399-1984

Secondary Contact: Ms. So Hyun Park, Regulatory Affairs Manager

Email: So.Park@glidewelldental.com

Phone: 949-863-5479

II. Device Name

Device Trade Name: Autoclavable Cassette (Glidewell HT™ Implant Guided Surgical Kit, Glidewell HT™ Implant Surgical Kit, Glidewell™ Prosthetic Kit)

Common Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

Classification Name: Sterilization Wrap

Regulation Number: 21 CFR 880.6850

Regulatory Class: Class II

Product Code: KCT

III. Predicate Device

Predicate 510(k) #: K180791

Predicate Trade Name: Straumann® BLX Surgical Cassette

Classification Name: Sterilization Wrap

Regulation Number: 21 CFR 880.6850

Regulatory Class: Class II

Product Code: KCT

IV. Device Description

The Autoclavable Cassettes are designed to store, organize, and protect various surgical and prosthetic instruments that are sterilized by the healthcare provider. The Autoclavable Cassettes are composed of three main components: a lid, a base, and a tray. The components are made of polyphenylsulfone PPSU. The tray has silicone rubber grommets to hold the instruments in place. The lid latches to the base. The base holds the tray, and all three components are designed to secure the kit into a single unit. The cassette protects the interior components during sterilization and subsequent storage. The kits are perforated to allow for penetration of moist heat during steam sterilization and require the use of an FDA-cleared sterilization wrap to maintain sterility. To facilitate the surgical procedure and the correct use and the positioning of the instrument, the tray has instrument descriptions on the surface.

Surgical and prosthetic instruments of the Glidewell Implant System are intended to be placed in the Autoclavable Cassette. These surgical and prosthetic instruments which are the contents of the sterilization cassette are all Class 1 exempt as described in 21 CFR 872.3980 (Endosseous dental implant accessories).

The Autoclavable Cassettes will be marketed in the following variations with accompanied instruments:

Device Model Name	Cassette Size	Max No. of Instruments	Weight of tray empty (g)	Weight of tray full (g)	Vent to Volume Ratio
Glidewell HT™ Implant Guided Surgical Kit	212mm x 173mm x 64mm	63	484	641	$3.11 X10^{-3}$ (mm^{-1}) 0.079 (in^{-1})
Glidewell HT™ Implant Surgical Kit	199mm x 174mm x 60mm	52	407	476	$6.09 X10^{-4}$ (mm^{-1}) 0.016 (in^{-1})
Glidewell™ Prosthetic Kit	96mm x 74mm x 60mm	11	163	192	$8.50 X10^{-4}$ (mm^{-1}) 0.022 (in^{-1})

V. Indications for Use

The Autoclavable Cassettes are used in healthcare facilities to organize surgical and prosthetic instruments during sterilization, storage, and transport during and after surgical uses. The Autoclavable Cassettes are not intended to maintain sterility; they are intended

to be used in conjunction with a legally marketed, validated sterilization wrap to maintain the sterility of the enclosed devices.

Sterilization parameters:

Pre-vacuum steam: 132°C (270° F) for 4 minutes with 30 minutes drying time.

Sterilization validations for the worst-case Autoclavable Cassette included cassette and instruments. The Autoclavable Cassettes were validated for a maximum load of 641 grams for Glidewell HT™ Implant Guided Surgical Kit, 476 grams for Glidewell HT™ Implant Surgical Kit, and 192 grams for Glidewell™ Prosthetic Kit.

VI. Technological Comparison

The subject device and predicate device share the following characteristics:

- Same intended use
- Same design
- Same principal of operation
- Same sterilization method
- Reusable

The subject device is technologically different from the predicate device as follows:

- Materials (same materials except medium size cassette which has a lid hinge pin made of stainless steel)
- Cassette size/weight
- Vent-to-Volume ratio
- Drying time

The technological characteristics of the subject device are compared to the predicate device in Table 1 below. Any noted differences in the technological characteristics between the subject device and the predicate device do not raise new concerns of safety and effectiveness.

Table 1: Comparison Table Between Subject Device and Predicate Device

Characteristics	Subject Device (K242564)	Predicate Device (K180791)	Comparison
Device Name	Autoclavable Cassette (Glidewell HT™ Implant Guided Surgical Kit, Glidewell HT™ Implant Surgical Kit, Glidewell™ Prosthetic Kit)	Straumann® BLX Surgical Cassette	N/A
Manufacturer	Prismatik Dentalcraft, Inc.	Straumann USA, LLC	N/A
Regulatory Classification			
Regulation Number	21 CFR 880.6850	21 CFR 880.6850	Same
Classification Name	Sterilization Wrap	Sterilization Wrap	Same
Classification	II	II	Same
Product Code	KCT	KCT	Same
Intended Use/Indication For Use			
Intended Use/ Indications for Use	The Autoclavable Cassettes are used in healthcare facilities to organize surgical and prosthetic instruments during sterilization, storage, and transport during and after surgical uses. The Autoclavable Cassettes are not intended to maintain sterility; they are intended to be used in conjunction with a legally marketed, validated sterilization wrap to maintain the sterility of the enclosed devices. Sterilization parameters: Pre-vacuum steam: 132°C (270° F) for 4 minutes with 30 minutes drying time. Sterilization validations for the worst-case Autoclavable Cassette included cassette and instruments. The Autoclavable Cassettes were validated for a maximum load of 641 grams for Glidewell HT™ Implant	The Straumann® BLX Cassette is used in healthcare facilities to organize, enclose, cleaning, sterilize, transport, and store medical devices between surgical uses. The BLX Cassette is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated sterilization wrap. The BLX Cassette has been validated for a maximum load of 300 grams, including cassette and instruments. Sterilization parameters: Pre-vacuum steam: 132°C (270° F) for 4 minutes with 20 minutes drying time.	Same; except for minor differences in the device trade name, and device size/weight.

Characteristics	Subject Device (K242564)	Predicate Device (K180791)	Comparison
	Guided Surgical Kit, 476 grams for Glidewell HT™ Implant Surgical Kit, and 192 grams for Glidewell™ Prosthetic Kit.		
Technological Characteristics			
Design	Plastic tray and lid	Plastic tray and lid	Same
Material	Polyphenylsulfone (Radel 5000) Silicon Stainless steel (lid hinge pin for medium size only)	Polyphenylsulfone (Radel 5000) Silicon	Same; except for the medium size of the subject device, which has a lid hinge pin made of stainless steel.
Material Compatible with Sterilization Method	Yes	Yes	Same
Perforated	Yes; Allow moist heat (steam) penetration to achieve sterilization.	Yes; Allow moist heat (steam) penetration to achieve sterilization.	Same
Enclosed Feature	Silicone grommets	Silicone grommets	Same
Reusable	Yes, up to 100x	Yes, up to 100x	Same
Sterilization Method	Moist heat (steam)	Moist heat (steam)	Same
Cycles	Pre-vacuum	Pre-vacuum	Same
Parameters	Pre-vacuum: 132°C (270° F) for 4 minutes with 30 minutes drying time.	Pre-vacuum: 132°C (270° F) for 4 minutes with 20 minutes drying time.	Similar; more drying time required for the subject device.
Sterile barrier	FDA cleared sterilization pouch	FDA cleared sterilization pouch	Same
Biocompatibility	The biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate the subject devices are non-cytotoxic.	The biocompatibility assessment was performed per ISO 10993-1 and testing was performed using methods described in ISO 10993-5. The results indicate the subject devices are non-cytotoxic.	Same

VII. Summary of Non-Clinical Testing

The performance during multiple reprocessing steps for Autoclavable Cassette, as recommended in the labeling, was validated according to applicable recommendations in the FDA guidance document - *Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015*. The worst-case cassettes were tested for performance based on critical impact factors including weight, vent to volume ratio, and worst-case instruments to be contained. The summary of performance testing is provided in Table 2 below.

Table 2. Performance Testing Summary

Type of Testing	Test Purpose	Acceptance Criteria	Test Result
Manual Cleaning Validation (ANSI/AAMI ST98:2022)	Evaluate and validate the manual cleaning of the subject device	• Visual Inspection: No visible soil • Hemoglobin Test: <2.2 µg/cm² • Protein Test: <6.4 µg/cm²	Pass
Sterilization Validation (ANSI/AAMI/ISO 17665-1:2006/ (R)2013)	Validate sterilization cycle and drying time of the subject devices	SAL $\leq 10^{-6}$ using the biological indicator (BI) overkill method	Pass
Reprocessing of Medical Devices in a Health Care Setting	Life Cycle (simulated use) testing after 100 cleaning and sterilization cycles	Test samples must withstand 100 cycles of use (cleaning, sterilization, and functional tests) without physical damage and compromising function.	Pass
Biocompatibility (ISO 10993-1:2018)	Chemical Characterization and Cytotoxicity	Cellular vitality for the extract of the sample >70%, which is considered non-cytotoxic.	Pass
Packaging Validation (ASTM D4169-23e1)	Packaging performance testing	Packaging must withstand the distribution environment.	Pass

PRISMATIK DENTALCRAFT, INC.

VIII. Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, cleared under K180791, Class II (21 CFR 880.6850), product code KCT.