



November 10, 2025

KLS-Martin L.P.
Pam Martin
Regulatory Affairs Project Manager
11201 Saint Johns Industrial Pkwy S
Jacksonville, Florida 32246

Re: K252573

Trade/Device Name: KLS-Martin Micro Osteosynthesis System; KLS Martin Centre-Drive Drill-Free Screw; KLS Martin Rigid Fixation – Sterile; Individual Patient Solutions – Ti (IPS-Ti); Individual Patient Solutions - PEEK (IPS-PEEK); Individual Patient Solutions - (IPS-PEEK)

Regulation Number: 21 CFR 882.5330

Regulation Name: Preformed Nonalterable Cranioplasty Plate

Regulatory Class: Class II

Product Code: GXN, JEY, HRS, GXP

Dated: August 14, 2025

Received: August 14, 2025

Dear Pam Martin:

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,

Jaime Raben -S

Jaime Raben, PhD

Director

DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices

OHT5: Office of Neurological and
Physical Medicine Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K252573

Device Name

KLS-Martin Micro Osteosynthesis System; KLS Martin Centre-Drive Drill-Free Screw; KLS Martin Rigid Fixation – Sterile; Individual Patient Solutions – Ti (IPS-Ti); Individual Patient Solutions - PEEK (IPS-PEEK); Individual Patient Solutions - (IPS-PEEK)

Indications for Use (Describe)

KLS-Martin Micro Osteosynthesis System (1.5MM):

The KLS-Martin Micro Osteosynthesis System (1.5MM) is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the segments.

KLS Martin Centre-Drive Drill-Free Screw:

The KLS Martin Centre-Drive Drill-Free Screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device referenced.

KLS Martin Rigid Fixation - Sterile:

The KLS Martin Rigid Fixation - Sterile is intended to provide, in sterile packaging, osteosynthesis products with the following indications for use:

- The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.
- The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.
- The KLS Martin Centre-Drive Drill-Free screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device reference
- The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.
- The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.

Individual Patient Solutions - Ti (IPS-Ti)*:

Individual Patient Solutions - Ti (IPS-Ti) is intended to replace bony voids in the mandibular, maxillofacial or craniofacial skeleton.

Individual Patient Solutions - PEEK (IPS-PEEK)*:

Individual Patient Solutions - PEEK (IPS-PEEK) is intended to replace bony voids in the cranial and/or craniofacial skeleton.

Individual Patient Solutions - (IPS-PEEK):**

The Individual Patient Solutions - (IPS-PEEK) is intended to replace bony voids in the cranial skeleton.

*Formerly known as "Patient Contoured Mesh"

**Formerly known as "Patient Contoured Implant"

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

21 CFR 807.92

Submitter: KLS-Martin L.P.
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Date Prepared: November 4, 2025

Trade Name: KLS-Martin Micro Osteosynthesis System
KLS Martin Centre-Drive Drill-Free Screw
KLS Martin Rigid Fixation – Sterile
Individual Patient Solutions – Ti (IPS-Ti)
Individual Patient Solutions - PEEK (IPS-PEEK)
Individual Patient Solutions - (IPS-PEEK)

Classification Regulation: 21 CFR 882.5330; Preformed nonalterable cranioplasty plate

Regulatory Class: II

Primary Product Code: GXN

Associated Product Codes: JEY, HRS, GXP

Predicate Devices: KLS-Martin Micro Osteosynthesis System (**K944565**)
KLS Martin Centre-Drive Drill-Free Screw (**K971297**)
KLS Martin Rigid Fixation – Sterile (**K060177**)
Individual Patient Solutions – Ti (IPS-Ti) (**K062570**)
Individual Patient Solutions - PEEK (IPS-PEEK) (**K072707**)
Individual Patient Solutions - (IPS-PEEK) (**K151382**)

Reference Device: Not applicable to this bundled 510(k) submission

Device Description:

KLS-Martin Micro Osteosynthesis System (1.5mm):

The KLS-Martin Micro Osteosynthesis System is designed to aid in the alignment and stabilization of the bones of the skeletal system after a facial fracture or surgery. The bone plate system is composed of bone plates and screws of various shapes and sizes for use in oral-maxillo-cranio-facial surgery. The bone plates are manufactured from CP Titanium and range in thickness from 0.3mm - 1.0mm. The bone screws are manufactured from Titanium Alloy and range in diameter from 1.5mm - 1.8mm.

KLS Martin Centre-Drive Drill-Free Screw:

The KLS Martin Centre-Drive Drill-Free Screws are designed to eliminate the need for pre-drilled pilot holes. They are self-tapping with one step insertion. They are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates where are contoured to fit the bony surface and stabilize the bone fragments. The bone screws are manufactured from Titanium Alloy and range in diameter from 1.0mm - 2.0mm.

KLS Martin Rigid Fixation - Sterile:

The KLS Martin Rigid Fixation - Sterile includes titanium plates of various shapes and thickness, titanium screws of various length and diameter, stainless steel twist drills of various length and diameter and stainless steel sonotrode tips that are provided in sterile packaging. The KLS Martin Rigid Fixation - Sterile is intended to provide KLS Martin's previously cleared osteosynthesis products in sterile packaging.

Individual Patient Solutions - Ti (IPS-Ti)*:

The Individual Patient Solutions - Ti (IPS-Ti) is a preformed implant manufactured from Titanium material. The implant is pre-shaped to fit the anatomy of the patient using a CT-based model of the patient's skull. The PCI-PEEK is fixated to native bone using previously cleared KLS Martin titanium plates and screws.

Individual Patient Solutions - PEEK (IPS-PEEK)*:

The Individual Patient Solutions - PEEK (IPS-PEEK) is a preformed implant manufactured from PEEK material. The implant is pre-shaped to fit the anatomy of the patient using a CT-based model of the patient's skull. The PCI-PEEK is fixated to native bone using previously cleared KLS Martin titanium plates and screws.

Individual Patient Solutions - (IPS-PEEK):**

The Individual Patient Solutions - (IPS-PEEK) is a preformed implant manufactured from PEEK material offered to the end-user as a sterile product. The implant is pre-shaped to fit the anatomy of the patient using a CT-based model of the patient's skull. The PCI-PEEK is fixated to native bone using previously cleared KLS Martin titanium plates and screws.

*Formerly known as "Patient Contoured Mesh"

**Formerly known as "Patient Contoured Implant"

Indications for Use:**KLS-Martin Micro Osteosynthesis System (1.5MM):**

The KLS-Martin Micro Osteosynthesis System (1.5MM) is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the segments.

KLS Martin Centre-Drive Drill-Free Screw:

The KLS Martin Centre-Drive Drill-Free Screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition

of the self drilling feature is the only difference between the submitted device and the predicate device referenced.

KLS Martin Rigid Fixation - Sterile:

The KLS Martin Rigid Fixation - Sterile is intended to provide, in sterile packaging, osteosynthesis products with the following indications for use:

- The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.
- The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.
- The KLS Martin Centre-Drive Drill-Free screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device reference
- The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.
- The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.

Individual Patient Solutions - Ti (IPS-Ti)*:

Individual Patient Solutions - Ti (IPS-Ti) is intended to replace bony voids in the mandibular, maxillofacial or craniofacial skeleton.

Individual Patient Solutions - PEEK (IPS-PEEK) *:

Individual Patient Solutions - PEEK (IPS-PEEK) is intended to replace bony voids in the cranial and/or craniofacial skeleton.

Individual Patient Solutions - (IPS-PEEK) **::

The Individual Patient Solutions - (IPS-PEEK) is intended to replace bony voids in the cranial skeleton.

*Formerly known as "Patient Contoured Mesh"

**Formerly known as "Patient Contoured Implant"

Technological Characteristics & Substantial Equivalence Discussion:

The indications for use for the subject and predicate devices are identical. The basis of this submission is to support the conditional safety and labeling modification of the subject device, KLS Martin Cranial Implants – MR Conditional, in the magnetic resonance environment.

The subject and predicate devices share identical technological characteristics which were previously evaluated in each predicate device included in this bundled submission. There

have been no significant changes to the previously cleared devices that would impact safety and effectiveness with regard to design, mechanical and engineering performance, manufacturing processes, materials, sterility, packaging and shelf life, and biocompatibility.

A device comparison table of the subject and predicate devices is provided below.

	KLS Martin Cranial Implants - MR Conditional	KLS-Martin Micro Osteosynthesis System (1.5MM) K944565	KLS Martin Centre-Drive Drill-Free Screw K971297	KLS Martin Rigid Fixation – Sterile K060177	Individual Patient Solutions - Ti (IPS-Ti) K062570	Individual Patient Solutions - PEEK (IPS-PEEK) K072707	Individual Patient Solutions - PEEK (IPS-PEEK) K151382
	(Subject Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)
Indications for Use	<p>Identical to the cleared predicate devices within this bundled submission:</p> <ul style="list-style-type: none"> • K944565 • K971297 • K060177 • K062570 • K072707 • K151382 	<p>The KLS-Martin Micro Osteosynthesis System (1.5MM) is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the segments.</p>	<p>The KLS Martin Centre-Drive Drill-Free Screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device referenced.</p>	<p>The KLS Martin Rigid Fixation - Sterile is intended to provide, in sterile packaging, osteosynthesis products with the following indications for use:</p> <p>K051236: The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.</p> <p>K032442: The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.</p> <p>K971297: The KLS Martin Centre-Drive Drill-Free screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device reference</p> <p>K944565: The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.</p> <p>K944561: The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone segments. The bone segments are attached to the plate with screws to prevent movement of the segments.</p>	<p>Patient Contoured Mesh (PCM) is intended to replace bony voids in the mandibular, maxillofacial or craniofacial skeleton.</p>	<p>Patient Contoured Mesh (PCM) - PEEK (PCM-P) is intended to replace bony voids in the cranial or craniofacial skeleton.</p>	<p>The Patient Contoured Implant – PEEK (PCI-PEEK) is intended to replace bony voids in the cranial skeleton.</p>

	KLS Martin Cranial Implants - MR Conditional	KLS-Martin Micro Osteosynthesis System (1.5MM) K944565	KLS Martin Centre-Drive Drill-Free Screw K971297	KLS Martin Rigid Fixation – Sterile K060177	Individual Patient Solutions - Ti (IPS-Ti) K062570	Individual Patient Solutions - PEEK (IPS-PEEK) K072707	Individual Patient Solutions - PEEK (IPS-PEEK) K151382
	(Subject Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)	(Predicate Device)
Classification	Class II	21 CFR 872.4760, Class II	21 CFR 888.3030, Class II	21 CFR 872.4760, Class II	21 CFR 882.5330, Class II	21 CFR 882.5330, Class II	21 CFR 882.5330, Class II
Product Code	GXN, GXP, JEY, HRS	JEY	HRS	JEY	GXN	GXN, GXP	GXN
Target Population	Refer to predicate devices; this is a bundled submission	Adult	Adult	Adult	Adult	Adult	Adult
Material	Refer to predicate devices; this is a bundled submission	CP Titanium or Ti-6Al-4V (Titanium Alloy)	Ti-6Al-4V (Titanium Alloy)	CP Titanium or Ti-6Al-4V (Titanium Alloy)	CP Titanium or Ti-6Al-4V (Titanium Alloy)	PEEK fixated with Ti screws and/or plates	PEEK fixated with Ti screws and/or plates
Sterilization	Non-sterile (steam) or Sterile (Gamma radiation)	Non-sterile (Steam)	Non-sterile (Steam)	Sterile (Gamma radiation)	Non-sterile (Steam)	Non-sterile (Steam)	Sterile (Gamma radiation)
MR Status	MR Conditional	N/A	N/A	N/A	N/A	N/A	N/A
Anatomical Sites	Cranial	Craniomaxillofacial	Craniomaxillofacial	Craniomaxillofacial	Craniomaxillofacial	Craniomaxillofacial	Cranial
Plate Specifications							
Thickness	Refer to predicate devices; this is a bundled submission	0.3mm – 1.0mm	N/A	Identical to K944565 & K971297	0.6mm – 1.0mm	<150 cm ² to >150 cm ²	<2500 mm ² to >25,000 mm ²
Screw Specifications							
Screw Diameter	Refer to predicate devices; this is a bundled submission	1.5mm – 1.8mm	1.0mm – 2.0mm	Identical to K944565 & K971297	1.5mm	1.0mm – 2.3mm	1.0mm – 2.3mm
Screw Length	Refer to predicate devices; this is a bundled submission	3.5mm – 15mm	2mm – 7mm	Identical to K944565 & K971297	2mm – 7mm	3.5mm – 15mm	3.5mm – 15mm
Screw Style	Refer to predicate devices; this is a bundled submission	Low Profile; Centre Drive, Cross-Drive, maxDrive; Drill-Free	Drill-Free; Centre Drive, Cross-Drive, maxDrive	Identical to K944565 & K971297	Low Profile; Centre Drive, Cross-Drive, maxDrive; Drill-Free	Low Profile; Centre Drive, Cross-Drive, maxDrive; Drill-Free	Low Profile; Centre Drive, Cross-Drive, maxDrive; Drill-Free

Performance Testing – Non-clinical:

Nonclinical testing has been provided to support the conditional safety of the subject devices in the MR environment. Hazards addressed include magnetically induced displacement force (ASTM F2052-21) and torque (ASTM F2213-17), image artifacts (ASTM F2119-07, R2013), and RF-induced heating (ASTM F2182-19e2).

Performance data demonstrate that KLS Martin Cranial Implants, when used in the MR environment using specified MR parameters and instructions, are not adversely affected by magnetically-induced displacement force and torque, RF-heating, and image artifacts.

Performance Testing – Clinical:

Clinical testing was not necessary for substantial equivalence determination.

Substantial Equivalence Conclusion:

Based on the results of the nonclinical testing and other supporting information, KLS Martin Cranial Implants can be safely scanned under the conditions presented in the labeling and has been demonstrated to be substantially equivalent to the predicate devices with respect to intended use, technological characteristics, and performance. Any differences in design or materials do not raise new questions of safety and effectiveness. Therefore, the subject device is as safe, effective, and performs as intended within the parameters of MR Conditional use as the legally marketed predicate devices.