August 17, 2026

KLS-Martin L.P.
Melissa Bachorski
Senior Director, RA/QMS North America
11201 Saint Johns Industrial Pkwy. S
Jacksonville, Florida 32246

Re: K260137
Trade/Device Name: KLS Martin IPS Oral-Max Implants - MR Conditional; Individual Patient Solutions - Ti (IPS-Ti); Individual Patient Solutions - PEEK (IPS-PEEK); KLS Martin Individual Patient Solutions
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZJ, LLZ, GXN, GXP
Dated: July 24, 2026
Received: July 24, 2026

Dear Melissa Bachorski:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANDREW I. STEEN -S

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K260137 |

Please provide the device trade name(s).

KLS Martin IPS Oral-Max Implants - MR Conditional;
K062570: Individual Patient Solutions - Ti (IPS-Ti);
K072707: Individual Patient Solutions - PEEK (IPS-PEEK) ;
K210731: KLS Martin Individual Patient Solutions

Please provide your Indications for Use below.

Individual Patient Solutions - Ti (IPS-Ti) (K062570)*:
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) (K072707)*:
Individual Patient Solutions - PEEK (IPS-PEEK) is intended to replace bony voids in the cranial and/or craniofacial skeleton.

KLS Martin Individual Patient Solutions (K210731):
KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery.

KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age - 21 years of age), and adults.

*Formerly known as "Patient Contoured Mesh"

| | |
|---|---|
| Please select the types of uses (select one or both, as applicable). | ☒ Prescription Use (21 CFR 801 Subpart D)<br>☐ Over-The-Counter Use (21 CFR 801 Subpart C) |

510(k) #: K260137

# 510(k) Summary

Prepared on: 2026-08-17

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | KLS-Martin L.P. |
| Applicant Address | 11201 Saint Johns Industrial Pkwy S Jacksonville FL 32246 United States |
| Applicant Contact Telephone | 904-641-7746 |
| Applicant Contact | Ms. Melissa Bachorski |
| Applicant Contact Email | rapm_na@klsmartin.com |
| Correspondent Name | KLS-Martin L.P. |
| Correspondent Address | 11201 Saint Johns Industrial Pkwy S Jacksonville FL 32246 United States |
| Correspondent Contact Telephone | 904-641-7746 |
| Correspondent Contact | Ms. Tugce Kalin |
| Correspondent Contact Email | rapm_na@klsmartin.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | KLS Martin IPS Oral-Max Implants - MR Conditional;<br>K062570: Individual Patient Solutions - Ti (IPS-Ti);<br>K072707: Individual Patient Solutions - PEEK (IPS-PEEK) ;<br>K210731: KLS Martin Individual Patient Solutions |
| Common Name | Bone plate |
| Classification Name | Plate, Bone |
| Regulation Number | 872.4760 |
| Product Code(s) | JEY, DZJ, LLZ, GXN, GXP |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K210731 | KLS Martin Individual Patient Solutions | JEY |
| K062570 | Individual Patient Solutions - Ti (IPS-Ti) f/k/a Patient Contoured Mesh | GXN |
| K072707 | Individual Patient Solutions - PEEK (IPS-PEEK) f/k/a Patient Contoured Mesh | GXN |
| K241314 | KLS Martin Oral-Max Implants MR Conditional (bundled) | JEY |

## Device Description Summary

21 CFR 807.92(a)(4)

Individual Patient Solutions - Ti (IPS-Ti) (K062570)*:
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 IPS-Ti is fixated to native bone using previously cleared KLS Martin titanium screws.

Individual Patient Solutions - PEEK (IPS-PEEK) (K072707)*:
The Individual Patient Solutions - PEEK (IPS-PEEK) is a preformed implant manufactured from PEEK material. The implant is preshaped to fit the anatomy of the patient using a CT-based model of the patient's skull. The IPS-PEEK is fixated to native bone using previously cleared KLS Martin titanium plates and screws.

KLS Martin Individual Patient Solutions (K210731):
KLS Martin Individual Patient Solutions (IPS) is comprised of a collection of software and associated additive manufacturing equipment intended to produce various outputs to support reconstructive and orthognathic surgeries. The system processes the medical images to produce various patient-specific physical and/or digital output devices which include implants, anatomical models, guides, splints, and case reports.

Patient-specific metallic bone plates are used in conjunction with metallic bone screws for internal fixation of maxillofacial, midface, and mandibular bones. The devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician provides input for model manipulation and interactive feedback by viewing digital models of planned outputs that are modified by trained KLS Martin engineers during the planning session. For each design iteration, verification is performed by virtually fittingthe generated output device over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

Implants are provided non-sterile and are manufactured using traditional (subtractive) or additive manufacturing methods from either CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136). These patient-specific devices are fixated with previously cleared KLS Martin screws.

*Formerly known as "Patient Contoured Mesh"

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Individual Patient Solutions - Ti (IPS-Ti) (K062570)*:
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) (K072707)*:
Individual Patient Solutions - PEEK (IPS-PEEK) is intended to replace bony voids in the cranial and/or craniofacial skeleton.

KLS Martin Individual Patient Solutions (K210731):
KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery.

KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age - 21 years of age), and adults.

*Formerly known as "Patient Contoured Mesh"

## Indications for Use Comparison

21 CFR 807.92(a)(5)

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 IPS Oral-Max Implants - MR Conditional, in the magnetic resonance environment.

## Technological Comparison

21 CFR 807.92(a)(6)

Similarities to the Predicate Devices

The subject and predicate devices have the same intended use, design, manufacturing methods, principles of operation, sterilization, packaging, and overall technological characteristics. The subject devices continue to be manufactured from commercially pure titanium and are intended for the same clinical applications as the legally marketed predicate devices.

Differences from the Predicate Devices

MR Environment Safety Information:
The subject device labeling differs from the predicate device labeling by adding safety information for use in the magnetic resonance environment. Non-clinical testing has been performed to support the conditional safety of the subject device 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).

Material Grade Change and Mechanical Performance:
The applicable IPS Trauma acute mandible trauma (AMT) implants include a material grade change from ASTM F67 commercially pure titanium Grade 2 to ASTM F67 commercially pure titanium Grade 4. No changes have been made to the implant design, dimensions, manufacturing process, compatible components, or intended use. The material grade is the only technological difference between the subject and predicate devices.

Comparative static and dynamic mechanical testing was performed on the worst-case device configuration using devices that were identical in design, dimensions, and manufacturing procedures, with the material grade being the only variable. The testing demonstrated that the material grade change does not negatively affect device performance and supports equivalent or improved mechanical performance compared to the previously cleared Grade 2 implants. Therefore, the material grade change does not raise different questions of safety or effectiveness.

Conclusion

Based on the technological comparison and the mechanical performance testing provided in this submission, the subject devices remain substantially equivalent to the legally marketed predicate devices.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical Testing:

MR Environment Safety Testing:
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 IPS Oral-Max 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.

Material Grade Change and Mechanical Performance Testing:
The applicable IPS Trauma acute mandible trauma (AMT) implants include a material grade change from ASTM F67 commercially pure titanium Grade 2 to ASTM F67 commercially pure titanium Grade 4. No changes have been made to the implant design, dimensions, manufacturing process, compatible components, or intended use. The material grade is the only technological difference between the subject and predicate devices.

Comparative static and dynamic mechanical testing was performed on the worst-case device configuration using devices that were identical in design, dimensions, and manufacturing procedures, with the material grade being the only variable. The testing demonstrated that the material grade change does not negatively affect device performance and supports equivalent or improved mechanical performance compared to the previously cleared Grade 2 implants. Therefore, the material grade change does not raise different questions of safety or effectiveness.

Clinical Testing:
Not Applicable

Conclusions:
Based on the results of the nonclinical testing and other supporting information, KLS Martin IPS Oral-Max 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.