



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

August 16, 2024

Re: K241314

Trade/Device Name: KLS Martin Oral-Max Implants MR Conditional (bundled)
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL, MQN, DZE, HRS, NEI
Dated: May 09, 2024
Received: July 18, 2024

Dear Katie Rutland:

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.

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,

Sherrill Lathrop Blitzer

for Andrew 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

Submission Number (if known)

K241314

Device Name

KLS Martin Oral-Max Implants - MR Conditional;
K943347: KLS Mini Osteosynthesis System;
K943348: KLS Chin Plate System;
K944561: KLS-Martin Micro Osteosynthesis System (1.0MM);
K944565: KLS-Martin Micro Osteosynthesis System (1.5MM);
K971297: KLS Martin Centre-Drive Drill-Free Screw;
K990667: KLS-Martin Temporary Condylar Implant;
K032442: KLS-Martin Mandibular/Reconstruction System II;
K033483: KLS-Martin Ortho Anchorage System;
K040891: KLS-Martin Ortho Anchorage System (Plates);
K060177: KLS Martin Rigid Fixation - Sterile;
K042573: KLS Martin Drill-Free MMF Screw;
K083432: Drill Free MMF Screw;
K173320: KLS Martin L1 MMF System

Indications for Use (Describe)

KLS Mini Osteosynthesis System (K943347):

The KLS Mini Osteosynthesis System is indicated for 1) Fractures, 2) Osteotomies, 3) Reconstruction procedures of the craniomaxillofacial skeletal system.

KLS Chin Plate System (K943348):

The KLS Chin Plate System is indicated for 1) Fractures, 2) Osteotomies, 3) Reconstruction procedures of the craniomaxillofacial skeletal system.

KLS-Martin Micro Osteosynthesis System (1.0MM) (K944561):

The KLS-Martin Micro Osteosynthesis System (1.0MM) 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 Micro Osteosynthesis System (1.5MM) (K944565):

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 (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 referenced.

KLS-Martin Temporary Condylar Implant (K990667):

The KLS-Martin Temporary Condylar Implant is only intended for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMF or traumatic injuries, or for treatment of temporomandibular joint

disease (TMD).

KLS-Martin Mandibular/Reconstruction System II (K032442):

The KLS-Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

KLS-Martin Ortho Anchorage System (K033483):

The KLS-Martin Ortho Anchorage System is intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures.

KLS-Martin Ortho Anchorage System (Plates) (K040891):

The KLS-Martin Ortho Anchorage System (Plates) are implants intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures in patients.

KLS Martin Rigid Fixation - Sterile (K060177):

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

K051236: The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.

K032442: The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

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

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.

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.

KLS Martin Drill-Free MMF Screw (K042573):

The KLS Martin Drill-Free MMF Screws is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.

Drill Free MMF Screw (K083432):

The Drill Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.

KLS Martin L1 MMF System (K173320):

The KLS Martin L1 MMF System is intended for temporary stabilization of mandibular and maxillary fractures. It is designed to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). It is indicated for the temporary treatment of maxillomandibular fixation (MMF) in adults or adolescents who have permanent teeth present (ages 12 and older).

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Correspondent Contact	Ms. Katie Rutland
Correspondent Contact Email	rapm_na@klsmartin.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	KLS Martin Oral-Max Implants - MR Conditional; K943347: KLS Mini Osteosynthesis System; K943348: KLS Chin Plate System; K944561: KLS-Martin Micro Osteosynthesis System (1.0MM); K944565: KLS-Martin Micro Osteosynthesis System (1.5MM); K971297: KLS Martin Centre-Drive Drill-Free Screw; K990667: KLS-Martin Temporary Condylar Implant; K032442: KLS-Martin Mandibular/Reconstruction System II; K033483: KLS-Martin Ortho Anchorage System; K040891: KLS-Martin Ortho Anchorage System (Plates); K060177: KLS Martin Rigid Fixation - Sterile; K042573: KLS Martin Drill-Free MMF Screw; K083432: Drill Free MMF Screw; K173320: KLS Martin L1 MMF System
Common Name	Bone plate
Classification Name	Plate, Bone
Regulation Number	872.4760
Product Code(s)	JEY, DZL, MQN, DZE

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
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K943347	KLS Mini Osteosynthesis System	JEY
K943348	KLS Chin Plate System	JEY
K944561	KLS-Martin Micro Osteosynthesis System	JEY
K944565	KLS-Martin Micro Osteosynthesis System	JEY
K971297	KLS Martin Centre-Drive Drill-Free Screw	HRS
K990667	KLS-Martin Temporary Condylar Implant	NEI
K032442	KLS-Martin Mandibular/Reconstruction System II	MQN
K033483	KLS-Martin Ortho Anchorage System	DZE
K040891	KLS-Martin Ortho Anchorage System (Plates)	DZE
K060177	KLS Martin Rigid Fixation - Sterile	JEY
K042573	KLS Martin Drill-Free MMF Screw	DZL
K083432	Drill Free MMF Screw	DZL
K173320	KLS Martin L1 MMF System	JEY

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

KLS Mini Osteosynthesis System (K943347):

The KLS Mini Osteosynthesis System consists of titanium non-locking plates ranging in thickness from 0.6mm - 2.5mm and titanium screws ranging in diameter from 1.5mm - 2.3mm.

KLS Chin Plate System (K943348):

The KLS Chin Plate System consists of titanium plates ranging in thickness of 0.6mm and titanium screws ranging in diameter from 1.5mm - 2.3mm.

KLS-Martin Micro Osteosynthesis System (1.0mm) (K944561):

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, bone screws and accessories 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 - 0.6mm. The bone screws are manufactured from Titanium Alloy and range in diameter from 1.0mm - 1.2mm.

KLS-Martin Micro Osteosynthesis System (1.5mm) (K944565):

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 - 0.6mm. The bone screws are manufactured from Titanium Alloy and range in diameter from 1.5mm - 1.8mm.

KLS Martin Centre-Drive Drill-Free Screw (K971297):

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 Temporary Condylar Implant (K990667):

The KLS-Martin Temporary Condylar Implant is a solid condylar head which attaches with fastening screws to a KLS-Martin Fracture/

Reconstruction Plate. The implant is available for left and right placement. The KLS-Martin Temporary Condylar Implant is only intended for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

KLS-Martin Mandibular/Reconstruction System II (K032442):

The KLS-Martin Mandibular/Reconstruction System II includes several different designs of titanium plates and screws intended for use in the stabilization and fixation of mandibular fractures and reconstruction. The plates are manufactured from either CP Titanium or Titanium Alloy and range in thickness from 1.0mm - 3.0mm. The screws are manufactured from either CP Titanium or Titanium Alloy and range in diameter from 2.0mm - 3.2mm.

KLS-Martin Ortho Anchorage System (K033483):

The KLS-Martin Ortho Anchorage System consists of a titanium screw designed to aid in dental movement by providing a rigid skeletal fixation point. The screw is intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures. The screws are manufactured from either CP Titanium or Titanium Alloy.

KLS-Martin Ortho Anchorage System (Plates) (K040891):

The KLS-Martin Ortho Anchorage System (Plates) consists of titanium non-locking plates to aid in dental movement by providing a rigid skeletal fixation point. The plates are manufactured from either CP Titanium or Titanium Alloy and are fixated with titanium screws and are utilized as an anchor for orthodontic procedures in the palatal, maxilla or mandible region.

KLS-Martin Drill-Free MMF Screw (K042573):

The KLS-Martin Drill-Free MMF Screw provides temporary occlusal and fracture stabilization. These screws may be applied prior to or after exposure of the fracture. The KLS-Martin Drill-Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both. The screws are manufactured from either CP Titanium or Titanium Alloy and are provided in 2.0mm diameter with lengths ranging from 8mm - 12mm.

KLS Martin Rigid Fixation - Sterile (K060177):

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.

Drill Free MMF Screw (K083432):

The Drill Free MMF Screw provides temporary occlusal and fracture stabilization. These screws may be applied prior to or after exposure of the fracture. The Drill Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both. The screws are manufactured from Stainless Steel and are provided in 2.0mm diameter with lengths ranging from 8mm - 12mm.

KLS Martin L1 MMF System (K173320):

The KLS Martin L1 MMF System is a bone-borne maxillomandibular fixation (MMF) system consisting of metallic archbars with sliding locking plates that attach to the dental arches with self-drilling locking screws. The system is intended to provide temporary stabilization of mandibular and maxillary fractures as well as maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). The patient is brought into occlusion by wiring around the archbar wire hooks. The L1 MMF system plates are manufactured from CP Titanium (ASTM F67), are available in either a 7-hole or 9-hole sliding plate configuration with two different lengths, and are 0.5mm in plate thickness. The L1 MMF system sliding locking plates are fixated with either 2.0 x 6 mm or 2.0 x 8 mm self-drilling locking screws manufactured from Ti-6Al-4V (ASTM F136). Implants are available both sterile and non-sterile. The system also includes the necessary instruments to facilitate placement of the implants.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

KLS Mini Osteosynthesis System (K943347):

The KLS Mini Osteosynthesis System is indicated for 1) Fractures, 2) Osteotomies, 3) Reconstruction procedures of the craniomaxillofacial skeletal system.

KLS Chin Plate System (K943348):

The KLS Chin Plate System is indicated for 1) Fractures, 2) Osteotomies, 3) Reconstruction procedures of the craniomaxillofacial skeletal system.

KLS-Martin Micro Osteosynthesis System (1.0MM) (K944561):

The KLS-Martin Micro Osteosynthesis System (1.0MM) 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 Micro Osteosynthesis System (1.5MM) (K944565):

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 (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 referenced.

KLS-Martin Temporary Condylar Implant (K990667):

The KLS-Martin Temporary Condylar Implant is only intended for temporary reconstruction of the mandibular condyle in patients who have undergone resective procedures to remove malignant or benign tumors requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMF or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

KLS-Martin Mandibular/Reconstruction System II (K032442):

The KLS-Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

KLS-Martin Ortho Anchorage System (K033483):

The KLS-Martin Ortho Anchorage System is intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures.

KLS-Martin Ortho Anchorage System (Plates) (K040891):

The KLS-Martin Ortho Anchorage System (Plates) are implants intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures in patients.

KLS Martin Rigid Fixation - Sterile (K060177):

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

K051236: The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.

K032442: The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

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

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.

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.

KLS Martin Drill-Free MMF Screw (K042573):

The KLS Martin Drill-Free MMF Screws is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.

Drill Free MMF Screw (K083432):

The Drill Free MMF Screw is intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both.

KLS Martin L1 MMF System (K173320):

The KLS Martin L1 MMF System is intended for temporary stabilization of mandibular and maxillary fractures. It is designed to maintain proper occlusion during intraoperative bone fixation and postoperative bone healing (app. 6-8 weeks). It is indicated for the temporary treatment of maxillomandibular fixation (MMF) in adults or adolescents who have permanent teeth present (ages 12 and older).

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

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.

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

Non-clinical 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).

Computational modeling and simulation (CM&S) was used to estimate ex-vivo and in-vivo temperature rise due to RF-induced heating for the entire portfolio of KLS Martin maxillofacial implants, which is the focus of this submission. Simulations of RF-induced heating at 1.5 T/64 MHz and 3 T/128 MHz were conducted in lieu of physical testing according to ASTM F2182-19e2 using MED Institute's FDA-qualified Medical Device Development Tool (MDDT) and in a clinically relevant position within the Duke virtual human anatomy. Various in-vivo device positions and landmarks of the Duke virtual human anatomy with the worst-case single and multiple devices were then simulated in 10 cm increments in each MRI system to determine the worst-case scenario for in-vivo RF-induced heating. The worst-case device, in-vivo position and landmark location for each MRI system for in-vivo RF-induced heating at a whole-body averaged specific absorption rate (wbSAR) of 2 W/kg or head SAR of 3.2 W/kg are determined. Fractional wbSAR or head SAR for an hour-long scanning session while maintaining a temperature rise of below 6 °C were determined for the worst-case devices within the Duke (Tables 3 to 12 in the test report) to align with the most recent FDA guidance document for testing and labeling of medical devices for safety in the magnetic resonance environment. Scanning conditions and guidelines for anatomical regions that can be safely scanned for an hour of continuous RF at wbSAR of 2 W/kg or head SAR of 3.2 W/kg were also determined. Therefore, the devices listed in the KLS Martin Oral-Max portfolio can be safely scanned under the conditions presented in the labeling.