December 11, 2024

TECHFIT Digital Surgery Inc.
Susana Munoz Cuartas
Regulatory Affairs Specialist
1511 Aviation Center Pkwy, Suite 220H
Daytona Beach, Florida 32114

Re: K242263
Trade/Device Name: TECHFIT DISRP® System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: September 12, 2024
Received: September 13, 2024

Dear Susana Munoz Cuartas:

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,

MICHAEL E. ADJODHA -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Respiratory, ENT, and Dental Devices
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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.

Submission Number *(if known)*

K242263

Device Name

TECHFIT DISRP® System

Indications for Use *(Describe)*

TECHFIT Digitally Integrated Surgical Reconstruction Platform (DISRP) System is intended for use as a software system 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 DISRP System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery. The DISRP System is also intended as a preoperative software tool for simulating / evaluating surgical treatment options.
The DISRP system is compatible with the TECHFIT Patient- Specific Maxillofacial System and the TECHFIT Diagnostic Models and should be used in conjunction with expert clinical judgment.

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.

1. 510(k) Summary

The 510(k) summary is provided on the following page per 21 CFR 807.92(c).

Traditional 510(k): Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92

1.1 Submitter information

Table 1. Submitter Information

Company name	TECHFIT Digital Surgery Inc.
Establishment registration number	3004187715
Street Address	1511 Aviation Center Pkwy Suite 220H
City	Daytona Beach
Zip code	FL 32114
Country	United States
Phone number	+57 604 322 33 75 Ext. 165
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Principal contact person	Susana Muñoz-Cuartas
Contact title	Regulatory Affairs Specialist
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Additional contact person	Angela María Lema-Pérez
Contact title	Regulatory Affairs Specialist
Contact e-mail address	angela.lema@techfitds.com

1.2 Date

December 10, 2024.

1.3 Submission information

Table 2. Submission Information

Trade name	TECHFIT DISRP® SYSTEM
Common or Usual name	DISRP
Classification name	21 CFR 872.4120 – Bone Cutting Instrument and Accessories
Product code (classification regulation)	DZJ, LLZ
Classification Panel	Dental
Device class	Class II

1.4 Predicate Device

Table 3. Predicate device

Predicate Device: KLS Martin Individual Patient Solutions (IPS) Planning system	
Trade or proprietary or model name	KLS Martin Individual Patient Solutions (IPS) Planning System
510(k) number	K182789
Decision date	2019/03/11
Product code	DZJ, LLZ
Manufacturer	KLS-Martin L.P.

1.5 Reference Devices

The general information of the reference devices is the following:

Table 4. General Information of the Reference Devices

Reference Devices		
1.	Trade or proprietary or model name 510 (k) number Decision date Product code Manufacturer	VSP® System K120956 2012/12/12 DZJ, LLZ Medical Modeling Inc.
2.	Trade or proprietary or model name 510 (k) number Decision date Product code Manufacturer	TECHFIT DISRP® System K230276 2023/06/23 DZJ, LLZ TECHFIT Digital Surgery, Inc.

3.	Trade or proprietary or model name 510 (k) number Decision date Product code Manufacturer	TECHFIT Patient-Specific Maxillofacial System K203282 2021/05/19 JEY Techfit Digital Surgery INC.
4.	Trade or proprietary or model name 510 (k) number Decision date Product code Manufacturer	AFFINITY Proximal Tibia System K220199 2022/03/21 HRS, HWC Industrias Medicas Sampedro S.A.S

1.6 Device Information

The following table presents the device information of the subject device and the predicate device.

Table 5. Device Information

	Subject device: DISRP® System (Palatal Splints and Anatomic Specificx Reconstruction Guides)	**Predicate Device: KLS Martin Individual Patient Solutions (IPS) Planning System**
Product code	DZJ, LLZ	DZJ, LLZ
Classification	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II
Intended Use	TECHFIT Digitally Integrated Surgical Reconstruction Platform (DISRP) System is intended for use as a software system 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 DISRP System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery. The DISRP System is also intended as a preoperative software tool for simulating / evaluating surgical treatment options. The DISRP system is compatible with the TECHFIT Patient- Specific Maxillofacial System and the TECHFIT Diagnostic Models and	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system 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 Planning System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

	should be used in conjunction with expert clinical judgment.	

1.7 Device Description

The **TECHFIT DISRP SYSTEM** is composed by Anatomic Specificx Guiding System and the Digitally Integrated Surgical Reconstruction Platform (DISRP).

- The **Digitally Integrated Surgical Reconstruction Platform (DISRP)** is a web-based collaboration software for digital surgery case flow management and Orthognathic surgery planning that reflects the production process and allows for the interaction of multiple users: surgeons, sales representatives, and the TECHFIT case planning staff (case planning assistant, case planners, and operations director), using multiple devices. It allows collaboration in the planning process. Detail description of the software can be found in later in this section.

- **Anatomic Specificx Guiding System** is a Patient-Specific single-use device designed to assist surgeons in transferring the pre-surgical plan to the operation room. This system includes surgical guides intended for Orthognathic and Reconstructive surgeries in adults. The surgical guides have drilling holes and slots to make osteotomies and ensure the correct positioning of bones and implants.

  The Anatomic Specificx Guiding System is divided into two categories: Anatomic Specificx Orthognathic Guides and Anatomic Specificx Reconstruction Guides.

  Anatomic Specificx Orthognathic Guides

  Anatomic Specificx Orthognathic Guides are classified into Titanium and Resin Surgical Guides.

  Anatomic Specificx Orthognathic **Titanium** Guides are manufactured from Commercially Pure (CP) Titanium grade 4; they include mandibular and maxillofacial surgical guides (e.g. Le Fort, Genioplasty, etc). Palatal Splints are also part of Anatomic Specificx Orthognathic Titanium Guides, which are optional guides used in orthognathic surgery to guide and support the correct teeth positioning and validate the patient's final occlusion.

  Anatomic Specificx Orthognathic **Resin** Guides are manufactured through rapid prototyping using the Form 3B and Form 4B printers and Biomed Clear Resin from Formlabs. These guides include Le Fort and genioplasty surgical guides. During surgery, resin surgical guides must be used with slot, drill, and screw metal sleeves. Slot sleeves are made from commercially pure grade 4 titanium, while drill and screw sleeves are made from alloyed titanium (Ti6Al4V). All sleeves are manufactured by machining. The resin guides also include splints (intermediate, final, and palatal), which are optional guides used in orthognathic surgery to guide and support the correct teeth positioning and validate the patient's final occlusion.

Anatomic Specificx Reconstruction Guides

The Anatomic Specificx Reconstruction Guides are intended for mandibular and maxillofacial surgical procedures in adults, using patient grafts/flaps for reconstruction. These guides are made from Commercially Pure (CP) grade 4 titanium, produced through machining and finished with an anodizing process. They are intended for use in the anatomical sites of the maxilla, mandible and fibula. The reconstruction guides provide transfer of the pre-surgical plan to the operating room, facilitating placement and fixation of the patient's bone grafts/flaps at the surgical site.

1.8 Indications for use

TECHFIT Digitally Integrated Surgical Reconstruction Platform (DISRP) System is intended for use as a software system 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 DISRP System, and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery. The DISRP System is also intended as a preoperative software tool for simulating / evaluating surgical treatment options.

The DISRP system is compatible with the TECHFIT Patient- Specific Maxillofacial System and the TECHFIT Diagnostic Models and should be used in conjunction with expert clinical judgment.

2. Comparison to Predicate Devices

Section 12 and Table 6 presents the comparison between the subject device, the predicate device, and the reference devices.

Table 6. Comparison Table

Characteristic	Subject device	Predicate Device	Reference Devices			
	DISRP® System (Anatomic Specificx Reconstruction Guides and Palatal Splints)	KLS Martin Individual Patient Solutions (IPS) Planning system	VSP® System	TECHFIT DISRP® System	TECHFIT Patient-Specific Maxillofacial system	AFFINITY Proximal Tibia System
510K Number	K242263	K182789	K120956	K230276	K203282	K220199

Intended use	TECHFIT Digitally Integrated Surgical Reconstruction Platform (DISRP) System is intended for use as a software system 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 DISRP System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery. The DISRP System is also intended as a preoperative software tool for	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system 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 Planning System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a	The Medical Modeling VSP® System is intended for use as a software system 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 VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	TECHFIT Digitally Integrated Surgical Reconstruction Platform (DISRP) System is intended for use as a software system 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 DISRP System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including surgical guides and splints for use in maxillofacial surgery. The DISRP System is also intended as a	TECHFIT Patient-Specific Maxillofacial System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.	AFFINITY Proximal Tibia System is intended to treat fractures, nonunions, malunions of the proximal tibia including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. -Simple metaphyseal fractures (Classification AO 41-A2). -Multifragmentary metaphyseal fractures (Classification AO 41-A3).

	simulating / evaluating surgical treatment options. The DISRP system is compatible with the TECHFIT Patient-Specific Maxillofacial System and the TECHFIT Diagnostic Models and should be used in conjunction with expert clinical judgment.	pre-operative software tool for simulating/evaluating surgical treatment options.		preoperative software tool for simulating / evaluating surgical treatment options. The DISRP system is compatible with the TECHFIT Patient- Specific Maxillofacial System and the TECHFIT Diagnostic Models and should be used in conjunction with expert clinical judgment.		-Simple bicondylar fractures (Classification AO41-C1, 41-C2). - Multifragmentary bicondylar fractures (Classification AO 41-C3). -Simple joint, simple metaphyseal fractures (Classification AO 41-C1). -Diaphisary fractures (Classification AO 42A and 42B).
Indications for use	Maxillofacial and Reconstruction Surgeries	Maxillofacial and Reconstruction Surgeries	Maxillofacial and Reconstruction Surgeries	Maxillofacial Surgeries	Maxillofacial and Reconstruction Surgeries	Orthopedic Surgery
Clinical Use	Maxillofacial	Maxillofacial	Maxillofacial	Maxillofacial	Maxillofacial / Midface & Mandible	Orthopedic Proximal Tibial Condyles
Product Code	DZJ, LLZ	DZJ, LLZ	DZJ, LLZ	DZJ, LLZ	JEY	HRS, HWC

Manufacturer	TECHFIT Digital Surgery, Inc.	KLS Martin	Medical Modeling Inc.	TECHFIT Digital Surgery, Inc.	TECHFIT Digital Surgery, Inc.	Industrias Medicas Sampedro S.A.S
Target Population	Adults	Pediatric & Adults	Adults	Adults	Adults	Adults
Patient-specific devices?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	No. The plates are standard manufactured plates

Material	Palatal Splints: CP Titanium. Anatomic Specificx Reconstruction: CP Titanium.	Anatomical Models: Epoxy/Resin, Acrylic. Cutting/Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium. Splints: methacrylate	Anatomic Models, templates, and surgical guides: Biocompatible polymers and surgical instrument grade stainless steel.	Anatomic Specificx Orthognathic Resin Guides (previously called "Resin Orthognathic Surgical Guides": Biomed Clear Resin. Anatomic Specificx Orthognathic Titanium Guides (previously called "Machined Orthognathic Surgical Guides": CP Titanium. Slot Metal sleeves: CP Titanium. Drill and Screw Metal Sleeves: CP Titanium and Alloyed Titanium (Ti6Al4V).	Plate: CP Titanium.	Plate: CP Titanium. Screw: Alloyed Titanium (Ti6Al4V).

Manufacturing Method	CP Titanium: Traditional (Subtractive).	Epoxy/Resin, Acrylic: Stereolithography (SLA). CP Titanium: Traditional (Subtractive). Ti-6Al-4V: 3D printing (Additive; Selective Laser Melting). Polyamide: 3D printing (Additive; Selective Laser Sintering).	3D printing	Resin: 3D printing - Stereolithography (SLA). CP Titanium and Alloyed Titanium: Traditional (Subtractive).	CP Titanium: Traditional (Subtractive).	CP Titanium and Alloyed Titanium: Traditional (Subtractive).
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)
Contact Duration	Palatal Splints: prolonged (24 h to 30 days). Anatomic Specificx Reconstruction: limited (≤ 24 h).	Limited (≤ 24 h).	Limited (≤ 24 h).	Limited (≤ 24 h).	Long Term (>30 days).	Long Term (>30 days).
Compatible with DISRP software?	Yes	No	No	Yes	Yes	No

Software changes	<u>Palatal Splints:</u> Include the new device visualization. <u>Anatomic Specificx Reconstruction Guides:</u> Include the reconstruction surgical guides visualization, fibula graft/flap, and mandible/maxilla visualization.	N/A	N/A	N/A	N/A	N/A
Image Import	DICOM data format from CT/CBCT scanner 3D models and surface scan data in generic open file format (STL)	DICOM data format from CT scanner 3D models and surface scan data in generic open file format (STL).	System Inputs: Images from medical scanners (i.e. CT)	DICOM data format from CT/CBCT scanner 3D models and surface scan data in generic open file format (STL)	DICOM data format from CT/CBCT scanner 3D models and surface scan data in generic open file format (STL)	N.A.
Software Output	Encrypted STL file with design of the final patient specific device such as surgical guides, splints and case reports	N/A	System Outputs: Physical and digital outputs such as patient specific anatomical models, cutting and drill guides, templates and splints	Encrypted STL file with design of the final patient specific device such as surgical guides, splints and case reports	N.A.	N.A.
Software Functions	3D Visualization	2D and 3D Visualization	3D Visualization	3D Visualization	N.A.	N.A.

Software Functions	Distance and angle measurements	Distance and angle measurements	Distance and angle measurements	Distance and angle measurements	N.A.	N.A.
	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies: Le Fort I, Chin, Splints, fibula	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies: Le Fort I, Sagittal, Splint, Ramus, Chin	The system uses electronic medical images of the patients' anatomy with input from the physician, to manipulate original patient images for planning and executing surgery. The system produces a variety of patient specific outputs including; anatomical models (physical and digital), surgical templates, guides, splints, and patient specific case reports.	Bone fragments can be moved in the 3D space (translations and rotations) in order to plan the ideal post-operative position of each fragment. Supported osteotomies: Le Fort I, Chin, Splint	N.A.	N.A.

Software Functions	3D Surgical Model creation from CBCT/CT scan data and STL file	3D Surgical Model creation from CT scan data	Commercial Off-The-Shelf (COTS) and custom software to manipulate 3-D medical scan images which can include Computed Tomography (CT), Cone Beam CT (CBCT), and/or 3-0 scan images from patient	3D Surgical Model creation from CBCT/CT scan data and STL file	N.A.	N.A.
	3D photo mapping	Soft tissue simulation	N.A.	3D photo mapping	N.A.	N.A.
	Based on the created orthognathic plan the user can export surgical guides and splints order files. These files can be used to calculate and produce orthognathic surgical guides and splints in the production backend	Based on the created orthognathic plan the user can export surgical splint order files. These files can be used to calculate and produce orthognathic splints in the production backend	N.A.	Based on the created orthognathic plan the user can export surgical guides and splints order files. These files can be used to calculate and produce orthognathic surgical guides and splints in the production backend	N.A.	N.A.

Software Functions	DISRP: the user can create a list of required osteosynthesis plates based on a created surgical plan.	N.A.	The system is made up of 13 individual pieces of software and 9 pieces of manufacturing equipment integrated to provide a range of anatomical models	DISRP: the user can create a list of required osteosynthesis plates based on a created surgical plan.	N.A.	N.A.

Software Functions	3D Cephalometry • Different types of 3D measurements (distances, angles, coordinates, etc.) • 3D visualization • Take snapshots to clipboard • Create reports • Perform cephalometric analysis on surgery models. • Remap landmarks • Visualize a set of key measurements, reconstruction guides and palatal splints • Check preoperative and planning values	N.A.	N.A.	3D Cephalometry • Different types of 3D measurements (distances, angles, coordinates, etc.) • 3D visualization • Take snapshots to clipboard • Create reports • Perform cephalometric analysis on surgery models. • Remap landmarks • Visualize a set of key measurements • Check preoperative and planning values	N.A.	N.A.

Operating system requirements	Operating system: Windows 64-bit (Windows 7 and/or later) Mac OS (Yosemite or later)	Windows 64-bit (Windows 7, 8, 10) Mac OS X (Yosemite, El Capitan)	Windows® 10 – 64bit Version 1909. Windows® 11 22H2. Microsoft Edge® or equivalent. PDF viewer. .NET framework 4.6.1 (or higher)	Operating system: Windows 64-bit (Windows 7 and/or later) Mac OS (Yosemite or later)	N.A.	N.A.

3. Performance data

The following non-clinical testing was conducted as a basis for the determination of substantial equivalence:

- Performance Data

Table 7. Overview of the Performance Data on the Subject Device

Name	Test Method	Conclusion
Validating sterilization methods	AAMI/ISO 17665-1:2006/(R)2013 Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices. ANSI/AAMI/ISO 14937:2009/(R)2013 Sterilization of Healthcare Products -General Requirements for Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.	The results of the steam sterilization validation show that Anatomic Specificx Reconstruction Guides and Palatal Splints sterilized to a SAL of 10-6 using the recommended steam sterilization instructions.
Dimensional validation	Scanning of Anatomic Specificx Reconstruction Guides and then comparing them versus the existing files.	The scanning comparison between the Anatomic Specificx Reconstruction Guides and the existing files was successful, meeting all acceptance criteria.
Compatibility testing	Verifying compatibility between Anatomic Specificx Reconstruction Guides, Patient-specific Maxillofacial System and TECHFIT Diagnostic Models. For palatal splints the compatibility between palatal splints, Anatomic Specificx Orthognathic Titanium Guides, TECHFIT Diagnostic Models and Patient-specific Maxillofacial System.	Anatomic Specificx Reconstruction Guides were compatible with Patient-specific Maxillofacial System and TECHFIT Diagnostic Models. Palatal Splints were compatible with Anatomic Specificx Orthognathic Titanium Guides, TECHFIT Diagnostic Models and Patient-specific Maxillofacial System.
Mechanical testing	Static and dynamic four-point bending mechanical tests were conducted on the	TECHFIT plates offer significantly greater resistance.

	Patient-specific Maxillofacial System, comparing TECHFIT plates to a mandibular plate from KLS Martin	
Software verification and validation activities	Verifying the item parts for the software	DISRP meets the SDS and testing as intended in the intended use environment. DISRP has a rigorous testing, and it is reviewing every time is deployed working as expected. V&V includes reliability and security processes.

- Biocompatibility Testing

An overview of biocompatibility testing is shown below:

Table 8. Biocompatibility Test Overview

Test / Assessment Description	Test Report Conclusion
Cytotoxicity test (ISO 10993-5)	No cytotoxic effect
Sensitization test (ISO 10993-10)	No sensitizing properties
Irritation/intracutaneous reactivity test (ISO 10993-10 and ISO 10993-23)	No irritant properties
Acute systemic toxicity (ISO 10993-11)	No evidence of systemic toxicity
Material-Mediated Pyrogenicity (ISO 10993-11)	No pyrogenic properties
Genotoxicity (ISO 10993-3)	No genotoxic potential
Chemical Characterization and risk assessment: ISO 10993-18 and ISO 10993-17	Non-toxic

4. Conclusion

Non-clinical tests demonstrate that the proposed changes to DISRP System is substantially equivalent to the predicate device.