June 23, 2023

TECHFIT Digital Surgery
Angela María Lema-Pérez
Regulatory Affairs Specialist
1511 Aviation Center Pkwy Suite 220H
Daytona Beach, Florida 32114

Re: K230276
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: May 30, 2023
Received: May 30, 2023

Dear Angela María Lema-Pérez:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Bobak
Shirmohammadi -S

For Michael E. Adjodha, M.ChE., CQIA
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230276

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 pre-operative 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.

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1 K230276 - 510(k) summary

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

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
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
Fax number	+57 604 3383013
Principal contact person	Angela María Lema-Pérez
Contact title	Regulatory Affairs Specialist
Contact e-mail address	angela.lema@techftids.com
Additional contact person	Susana Muñoz-Cuartas
Contact title	Regulatory Affairs Specialist
Contact e-mail address	susana.munoz@techfitds.com

1.2 Date Prepared

June 22, 2023.

1.3 Submission information

Table 2. Submission information

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

1.4 Predicate device

The primary devices to which substantial equivalence is claimed to:

Table 3. Primary predicate device

Primary predicate: 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. Reference Device 1

Secondary predicate: IPS CaseDesigner 2.0	
Trade or proprietary or model name	IPS CaseDesigner 2.0
510(k) number	K200810
Decision date	2020/10/08
Product code	LLZ
Manufacturer	Nobel Biocare AB

Table 5. Reference Device 2

Reference device 1: TECHFIT Patient-Specific Maxillofacial System	
Trade or proprietary or model name	TECHFIT Patient-Specific Maxillofacial System
510(k) number	K203282
Decision date	2021/05/19
Product code	JEY
Manufacturer	TECHFIT Digital Surgery INC.

Table 6. Reference Device 3

Reference device 2: AFFINITY Proximal Tibia System	
Trade or proprietary or model name	AFFINITY Proximal Tibia System
510(k) number	K220199
Decision date	2022/03/21
Product code	HRS, HWC
Manufacturer	Industrias Medicas Sampedro S.A.S

1.6 Device Information

Table 7 presents the device information of the subject device and predicate devices.

Table 7. Device information

	Subject device: TECHFIT DISRP® SYSTEM	**Primary predicate device: KLS Martin Individual Patient Solutions (IPS) Planning System (K182789)**
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	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system and image segmentation

	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 pre-operative 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	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.

1.6.1 Device Description

The **TECHFIT DISRP SYSTEM** is composed by **Orthognathic Surgical Guides** and the **Digitally Integrated Surgical Reconstruction Platform (DISRP).**

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 easy collaboration in the planning process. Being web-based allows immediate and convenient sharing without the installation or maintenance of the application at the user's end.

Orthognathic Surgical Guides

Orthognathic Surgical Guides are Patient-Specific single use devices that are designed to assist the surgeon in transferring the pre-surgical plan to the operation room. Surgical Guides are intended for Orthognathic surgeries in adults and have drilling holes and slots for making drillings and osteotomies, as well as they guide the correct positioning of bones and implants.

Orthognathic Surgical Guides is divided into two types: Resin Orthognathic Surgical Guides and Machined Orthognathic Surgical Guides.

- Resin Orthognathic Surgical Guides

Resin Orthognathic Surgical Guides include **surgical guides** and **splints.**

Surgical Guides consist of the Le Fort and Genioplasty surgical guides, which are composed of a body that is manufactured by TECHFIT Digital Surgery and produced by rapid prototyping with the Form 3B printer and Biomed Clear Resin from Formlabs, Somerville, United States.

In surgery **Surgical Guides** must be used with **Metal Sleeves**. There are three types of metal sleeves: slot metal sleeve, drill metal sleeve and screw metal sleeve. The slot, drill and screw metal sleeves are manually fitted by the healthcare professional during surgery into the slots, drilling holes and fixation holes of the surgical guide. The metal sleeves are produced from commercially pure titanium grade 4 through machining and are manufactured equivalent to the TECHFIT Patient-Specific Maxillofacial System (K203282) and AFFINITY Proximal Tibia System (K220199). In addition, the Metal Sleeves are single-use and patient-specific accessories.

The **Splints** are optional guides used in orthognathic surgery to guide to the correct teeth positioning and to validate the patient's final occlusion. The **Splints** are manufactured by TECHFIT Digital Surgery and produced by rapid prototyping using the Form 3B printer and Biomed Clear Resin from Formlabs, Somerville, United States.

- Machined Orthognathic Surgical Guides

Machined Orthognathic Surgical Guides consist of the Le Fort and Genioplasty surgical guides that are manufactured from the same material (commercially pure titanium grade 4) and in a manufacturing process equivalent to the TECHFIT Patient-Specific Maxillofacial System (K203282) and AFFINITY Proximal Tibia System (K220199) manufactured through machining.

Machined Orthognathic Surgical Guides and **Metal Sleeves** are manufactured with the same material and same manufacturing process.

1.6.2 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 pre-operative 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

Both subject device and primary predicate have the same indications for use: orthognathic surgery, including Le Fort and Genioplasty Surgical Guides and splints, reconstructive surgery, and trauma of the midface and maxillofacial skeleton. A device comparison table is more detailed in section 12 and Table 8.

Table 8. Comparison to predicate device - an overview.

Criteria	Subject device	Primary predicate	Reference device 1	Reference device 2	Reference device 3
	TECHFIT DISRP® SYSTEM	**KLS Martin Individual Patient Solutions (IPS) Planning System**	**IPS CaseDesigner 2.0**	**TECHFIT Patient-Specific Maxillofacial system**	**AFFINITY Proximal Tibia System**
510K number	**K230276**	**K182789**	**K200810**	**K203282**	**K220199**

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 pre-operative software tool for simulating / evaluating surgical treatment options.	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	IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.	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)

	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	surgical treatment options.			-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)
Clinical Use	Orthognathic treatment	Maxillofacial and orthognathic treatment	Cranio-maxillofacial and orthognathic treatment	Maxillofacial/ Midface & Mandible	Orthopedic Proximal tibial condyles
Product Code	DZJ, LLZ	DZJ, LLZ	LLZ	JEY	HRS, HWC

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	21 CFR 892.2050, Class II	21 CFR 872.4760, Class II	21 CFR 888.3030, Class II
Target Population	Adults	Pediatric & Adults	Adults	Adults	Adults
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).	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)	No
Software output	Encrypted STL file with design of the final patient specific device such as surgical guides, splints and case reports	N.A.	Encrypted STL file with design of the final splint for centralized manufacturing at KLS Martin	N.A	N.A
	3D Visualization	2D and 3D Visualization	2D and 3D Visualization	N.A	N.A
	Distance and angle measurements	Distance and angle measurements	Distance and angle measurements	N.A	N.A

Software functions	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	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	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, Segmental (Split, Y-cut, H-cut)	N.A	N.A
	3D Surgical Model creation from CBCT/CT scan data and STL file	3D Surgical Model creation from CT scan data	3D Surgical Model creation from CBCT/CT scan data and STL file	N.A	N.A
	3D photo mapping	Soft tissue simulation	Soft tissue simulation, 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	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	N.A
	DISRP: the user can create a list of required osteosynthesis plates based on a created surgical plan.	N.A.	Osteosynthesis Plates & IPS Gate: the user can create a list of required osteosynthesis plates based on a created surgical plan.	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 pre-operative and planning values	N.A.	3D Cephalometry • Different types of 2D/3D measurements (distances, angles, coordinates, etc.) • 2D/3D visualization • Take snapshots to clipboard • Create/export reports Perform cephalometric analysis on surgery models. • Remap landmarks • Visualize a set of key measurements • Check pre-operative and planning values	N.A	N.A

	- New algorithm for occlusion alignment - New algorithm for virtual occlusion	N.A.	• New algorithm for occlusion alignment • - New algorithm for virtual occlusion	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 64-bit (Windows 7, 10) Mac OS Catalina, Mojave, High Sierra	N.A	N.A
Material	Resin Orthognathic Surgical guides: Biomed Clear Resin. Machined Orthognathic Surgical Guides: CP Titanium. Metal sleeves: CP Titanium.	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium Splints: methacrylate	Not available	CP Titanium	CP Titanium

Manufacturing Method	Resin: 3D printing - Stereolithography (SLA). CP Titanium: Traditional (Subtractive)	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting) Polyamide: 3D (Additive; Selective Laser Sintering)	Not available	Traditional (Subtractive)	Traditional (Subtractive)
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Not available	Non-sterile (Steam)	Non-sterile (Steam)
Manufacturer	TECHFIT Digital Surgery	KLS Martin	Nobel Biocare	TECHFIT Digital Surgery	Industrias Médicas Sampedro
Patient-specific configuration?	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	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient	No. The plates are standard manufactured plates

3 Performance data

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

Table 9. Performance data

Name	Test method	Conclusion
Safety testing		
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 TECHFIT Orthognathic Surgical Guides sterilized to a SAL of 10-6 using the recommended steam sterilization instructions
Performance testing		
Dimensional validation	Scanning of orthognathic surgical guides and then comparing them versus the original files, before and after sterilization.	DISRP and Orthognathic surgical guides maintain the proportions and dimensions of the original digital design after manufacturing and sterilization.
Mechanical testing	Bending and compressive strength, after sterilization. Evaluating if the orthognathic surgical guides can withstand the maximum bite force, force required for drilling and handle force required for a general surgery.	Orthognathic Surgical Guides withstand bit force and the force applied by the surgeon during handling.
Compatibility testing	Verifying compatibility between the Maxillofacial System and orthognathic surgical guides	Orthognathic Surgical Guides are compatible with the Maxillofacial System and Metal Sleeves.
Software testing	Software verification and validation activities	DISRP software was verified and validated as per IEC 62304

- Biocompatibility testing

Resin Orthognathic Surgical Guides are manufactured with Biomed Clear (Formlabs). The following are the tests summarizes the biocompatibility testing:

Table 10. Overview of Biomed Clear biocompatibility testing

Test / Assessment Description	Test Report Conclusion
Cytotoxicity: ISO 10993-5	No cytotoxic effect properties in compliance with requirements of the ISO 10993-5 guidelines
Sensitization: ISO 10993-10	No sensitizing properties in compliance with requirements of the ISO 10993-10 guidelines
Irritation: ISO 10993-10	No irritant properties in compliance with requirements of the ISO 10993-10 guidelines
Acute systemic toxicity: ISO 10993-11 and USP <88>	No evidence of systemic toxicity test passed and is considered negative based on standards set by ISO 10993-11
Pyrogenicity: ISO 10993-11	No pyrogenic properties in compliance with requirements of the ISO 10993-11
Chemical Characterization and risk assessment: ISO 10993-18 and ISO 10993-17	Non-toxic chemical characterization as per ISO 10993-18 and ISO 10993-17 standards

An overview of TECHFIT's biocompatibility testing is shown below:

Table 11. Overview of TECHFIT biocompatibility testing for Resin Orthognathic Surgical Guides

Test / Assessment Description	Test Report Conclusion
Cytotoxicity: ISO 10993-5	No cytotoxic effect properties in compliance with requirements of the ISO 10993-5 guidelines
Sensitization: ISO 10993-10	No sensitizing properties in compliance with requirements of the ISO 10993-10 guidelines
Irritation: ISO 10993-23	No irritant properties in compliance with requirements of the ISO 10993-10 guidelines

Machined Orthognathic Surgical Guides and Metal Sleeves are manufactured with commercially pure Titanium grade 4. The following are the tests summarizes the biocompatibility testing:

Table 12. Overview of TECHFIT biocompatibility testing for Machined Orthognathic Surgical Guides and Metal Sleeves.

Test / Assessment Description	Test Report Conclusion
Cytotoxicity: ISO 10993-5	No cytotoxic effect properties in compliance with requirements of the ISO 10993-5 guidelines
Sensitization: ISO 10993-10	No sensitizing properties in compliance with requirements of the ISO 10993-10 guidelines
Irritation: ISO 10993-10	No irritant properties in compliance with requirements of the ISO 10993-10 guidelines
Acute systemic toxicity: ISO 10993-11	No evidence of systemic toxicity test passed and is considered negative based on standards set by ISO 10993-11
Pyrogenicity: ISO 10993-11	No pyrogenic properties in compliance with requirements of the ISO 10993-11
Genotoxicity: ISO 10993-3	No genotoxicity properties in compliance with requirements of the ISO 10993-3
Chemical Characterization and risk assessment: ISO 10993-18 and ISO 10993-17	Non-toxic chemical characterization as per ISO 10993-18 and ISO 10993-17 standards

4 Conclusion

Non-clinical tests demonstrate that the DISRP System is substantially equivalent to the predicate devices.