



October 27, 2025

TECHFIT Digital Surgery Inc.  
Angela Lema  
Regulatory Affairs Specialist  
1511 Aviation Center Pkwy, Suite 220H  
Daytona, Florida 32114

Re: K250297

Trade/Device Name: TECHFIT Patient-Specific Cranial System  
Regulation Number: 21 CFR 882.5320  
Regulation Name: Preformed Alterable Cranioplasty Plate  
Regulatory Class: Class II  
Product Code: GWO  
Dated: September 26, 2025  
Received: September 26, 2025

Dear Angela Lema:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Adam D.  
Pierce -S**

Digitally signed by  
Adam D. Pierce -S  
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13:38:20 -04'00'

Adam D. Pierce, Ph.D.  
Assistant Director  
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Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known)  
K250297

Device Name  
TECHFIT Patient-Specific Cranial System

Indications for Use (Describe)

The TECHFIT Patient-Specific Cranial System is intended to replace bony voids in the cranial skeleton. The devices are indicated for adults and adolescents from 18 years or 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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**Traditional 510(K) – Summary**

*Table of Contents*

- 1. 510(k) summary ..... 2
  - 1.1 Submitter information ..... 2
  - 1.2 Submission date ..... 2
  - 1.3 Submission information ..... 2
  - 1.5 Predicate device ..... 3
  - 1.6 Reference devices ..... 3
  - 1.7 Device Information ..... 5
  - 1.8 Device Description ..... 5
  - 1.9 Indications for use ..... 6
- 2. Comparison of Predicate Device ..... 6
  - 2.1. Similarities ..... 6
  - 2.2. Differences from the predicate device ..... 7
- 3. Performance data ..... 13
- 4. Conclusion ..... 16

### 1. 510(k) summary

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

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 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	Angela Maria Lema-Perez
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Additional contact person	Susana Muñoz
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Contact e-mail address	susana.munoz@techfitds.com

#### 1.2 Submission date

Date of the 510(k): 31<sup>st</sup> January 2025.

#### 1.3 Submission information

Table 2. Submission Information – Subject device

Trade name	TECHFIT Patient-Specific Cranial System
Common or Usual name	Cranioplasty
Classification name	Plate, Cranioplasty, Preformed, Alterable

Product code (classification regulation)	GWO
Classification Panel	Neurology, Radiology
Device class	Class II

### 1.5 Predicate device

Table 3. Predicate device

Predicate Device: Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)	
Trade or proprietary or model name	Synthes Patient Specific Cranial/Craniofacial Implant (PSCI)
510(k) number	K053199
Decision date	12/14/2005
Product code	GXN
Manufacturer	Synthes (USA)

### 1.6 Reference devices

The general information of the reference devices is the following:

Table 4. Reference device 1

Reference device 1: OsteoFab™ Patient Specific Cranial Device Samples	
Trade or proprietary or model name	OsteoFab™ Patient Specific Cranial Device Samples
510(k) number	K121818
Decision date	18/18/2012
Product code	GXN
Manufacturer	Oxford Performance Materials, LLC
Review panel	Neurology

Table 5. Reference device 2

Reference device 2: LeForte Neuro System Bone Plate & Screw	
Trade or proprietary or model name	LeForte Neuro System Bone Plate & Screw

510(k) number	K141452
Decision date	07/02/2014
Product code	OWO, GXR. HBW
Manufacturer	Jeil Medical Corporation
Review panel	Neurology

Table 6. Reference device 3

Reference device 3: TECHFIT DISRP® System	
Trade or proprietary or model name	TECHFIT DISRP® System
510(k) number	K230276
Decision date	06/23/2023
Product code	DZJ, LLZ
Manufacturer	TECHFIT Digital Surgery
Review panel	Dental

Table 7. Reference device 4

Reference device 4: TECHFIT Diagnostic Models	
Trade or proprietary or model name	TECHFIT Diagnostic Models
510(k) number	K222577
Decision date	06/01/2023
Product code	LLZ
Manufacturer	TECHFIT Digital Surgery
Review panel	Dental

Table 8. Reference device 5

Reference device 5: ANATOMIC PEEK™ Cervical Fusion System	
Trade or proprietary or model name	Anatomic PEEK™ Cervical Fusion System
510(k) number	K192502

Decision date	11/22/2019
Product code	MAX, OVD, ODP, OVE, MQP, PLR
Manufacturer	Medtronic Sofamor Danek USA, Inc
Review panel	Orthopedic

### 1.7 Device Information

Table 9 presents the device information of the subject device and predicate device.

Table 9. Device Information

	<b>Subject device: Techfit Patient-Specific Cranial System</b>	<b><i>Predicate device: Synthes Patient Specific Cranial/Craniofacial Implants</i></b>
Product code	GWO	GXN
Classification	21 CFR 882.5320, Class II	21 CFR 882.5330, Class <i>II</i>
Intended Use	The TECHFIT Patient-Specific Cranial System is intended to replace bony voids in the cranial skeleton. The devices are indicated for adults and adolescents from 18 years or older.	The Synthes (USA) Patient Specific Cranial/Craniofacial Implant is intended to replace bony voids in the cranial/craniofacial skeleton.

### 1.8 Device Description

The TECHFIT Patient-Specific Cranial System is patient specific devices intended to replace bony voids in the cranial/craniofacial skeleton. The TECHFIT Patient-Specific Cranial System includes a cranial implant, cranial model and a software component for digital planning and visualization named Digitally Integrated Surgical Reconstruction Platform DISRP®.

TECHFIT Patient-Specific Cranial Implants are manufactured from Polyether Ether Ketone (PEEK). The TECHFIT Patient-Specific Cranial Implants are attached to the native bone using commercial plates and screws.

The TECHFIT Patient-Specific Cranial System matches the shape and dimensions of the missing skull bone fragments. The implants are manufactured from PEEK according to ASTM F2026 and are manufactured by machining process.

The TECHFIT Patient-Specific Cranial System models are patient specific devices manufactured from clear resin using 3D printing manufacturing process. Those models are a representation of the anatomy of the patient, and they are not indicated to enter to the OR (Operating Room).

**1.9 Indications for use**

The TECHFIT Patient-Specific Cranial System is intended to replace bony voids in the cranial skeleton.

The devices are indicated for adults and adolescents from 18 years or older.

**2. Comparison of Predicate Device**

**2.1. Similarities**

**Intended use:** equivalent

The subject device and the predicate device share similar intended use and are intended for the same anatomical region. Table 10 demonstrates intended use equivalence.

*Table 10. TECHFIT patient-specific Cranial Implant and Synthes Patient Specific Cranial/Craniofacial Implant (PSCI) intended use equivalence.*

<b>Subject device</b>	<b>Predicate device</b>
Techfit Patient-Specific Cranial System	Synthes Patient Specific Cranial/Craniofacial Implants
<p>The TECHFIT Patient-Specific Cranial System is intended to replace bony voids in the cranial skeleton.</p> <p>The devices are indicated for adults and adolescents from 18 years or older.</p>	<p>The Synthes (USA) Patient Specific Cranial/Craniofacial Implant is intended to replace bony voids in the cranial/craniofacial skeleton.</p>

**Patient-specific configuration:** equivalent

The subject device and the predicate device are manufactured specifically to match the patient's anatomy. The design process for both the subject and the predicate device starts from a patient's CT scan, taken according to a specific CT scan protocol.

**System fixation:** equivalent

The subject device and the predicate device are designed and manufactured with integrated screw holes to fixate the device to the bone using bone screws or plates.

**Sterility:** equivalent

The subject and predicate devices are all provided non-sterile and must be sterilized by moist heat prior to surgery.

**Manufacturing method:** equivalent

Both, subject and predicate, have the same manufacturing method by CNC machining.

**Material:** equivalent

The subject and the predicate devices plates are made from PEEK.

## 2.2. Differences from the predicate device

TECHFIT implants differ in that they are indicated for use in adults and adolescents aged 18 years or older, while the Synthes device is indicated for adult patients only.

The TECHFIT Patient-Specific Cranial System differs from the predicate device, the Synthes Patient Specific Cranial/Craniofacial Implant (PSCI), by including an anatomical model and a software component, the Digitally Integrated Surgical Reconstruction Platform (DISRP®). While the predicate device solely comprises, implantable components designed to replace bony voids in the cranial skeleton, the TECHFIT system incorporates an anatomical model to enhance preoperative planning. Additionally, the DISRP® software provides digital planning and a 3D viewer to optimize implant design, surgical procedures and facilitates the customization of both the implant and the anatomical model, and DISRP® System is a system that includes not only software but also orthognathic surgical guides, and these guides are not part of the Cranial System submission. These differences reflect advancements in patient-specific medical device technology, enhancing surgical workflow and precision while maintaining the fundamental purpose of cranial reconstruction.

TECHFIT implants differ from the predicate device because the predicate device includes titanium cranial implants.

Table 11 shows the details of the subject, predicate and reference devices.

Table 11. Comparison table

Characteristic / Name of the device	Subject device <b>TECHFIT Patient-Specific Cranial Implants System</b>	Predicate device <b>Synthes Patient Specific Cranial/Craniofacial Implant</b>	Reference device # 1 <b>OsteoFab™ Patient Specific Cranial Device</b>	Reference device # 2 <b>LeForte Neuro, System Bone Plate &amp; Screw</b>	Reference device # 3 <b>TECHFIT DISRP® System</b>	Reference device # 4 <b>TECHFIT Diagnostic Models</b>	Reference device # 5 <b>ANATOMIC PEEK™ Cervical Fusion System</b>
510K number	K250297	K053199	K121818	K141452	K230276	K222577	K192502
Intended Use	<p>The TECHFIT Patient-Specific Cranial System is intended to replace bony voids in the cranial skeleton.</p> <p>The devices are indicated for adults and adolescents from 18 years.</p>	<p>The Synthes (USA) Patient Specific Cranial/Craniofacial Implant is intended to replace bony voids in the cranial/craniofacial skeleton.</p>	<p>The OsteoFab™ Patient Specific Cranial Device (OPSCD) intended for the replacement of bony voids in the cranial skeleton</p>	<p>This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.</p>	<p>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</p>	<p>The TECHFIT Diagnostic Models are patient-specific devices intended to be used as a pre-operative planning tool for treatment in the field of maxillofacial surgery. The input data file (DICOM imaging information from a medical scanner file) is processed by commercial off-the-shelf</p>	<p>The ANATOMIC PEEK™ Cervical Fusion System is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates</p>

Characteristic / Name of the device	Subject device TECHFIT Patient-Specific Cranial Implants System	Predicate device Synthes Patient Specific Cranial/Craniofacial Implant	Reference device # 1 OsteoFab™ Patient Specific Cranial Device	Reference device # 2 LeFort Neuro, System Bone Plate & Screw	Reference device # 3 TECHFIT DISRP® System	Reference device # 4 TECHFIT Diagnostic Models	Reference device # 5 ANATOMIC PEEK™ Cervical Fusion System
					<p>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 /</p>	<p>software, and the result is an output data file that may then be provided as digital models or used as input to produce physical anatomic models using additive manufacturing. The physical replica can be used for diagnostic purposes in the field of, maxillofacial applications. TECHFIT Diagnostic Models should be used in conjunction with other diagnostic tools and expert clinical judgment. TECHFIT Diagnostic</p>	<p>producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC PEEK device is to be used with supplemental fixation. The ANATOMIC PEEK cervical fusion system is also required to be used with autogenous bone and/or allograft bone graft comprised of cancellous and/or corticocancellous bone graft, and/or demineralized allograft bone with</p>

Characteristic / Name of the device	Subject device TECHFIT Patient-Specific Cranial Implants System	Predicate device Synthes Patient Specific Cranial/Craniofacial Implant	Reference device # 1 OsteoFab™ Patient Specific Cranial Device	Reference device # 2 LeForte Neuro, System Bone Plate & Screw	Reference device # 3 TECHFIT DISRP® System	Reference device # 4 TECHFIT Diagnostic Models	Reference device # 5 ANATOMIC PEEK™ Cervical Fusion System
					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.	Models are not intended to enter the operating room	bone marrow aspirated and is to be implanted via open anterior approach.
Product code	GWO	GXN	GXN	GWO, GXR, HBW	DZJ, LLZ	LLZ	MAX, OVD, ODP, OVE, MQP, PLR
Classification	Class II	Class II	Class II	Class II	Class II	Class II	Class II
Regulation Number	21 CFR 882.5320	21 CFR 882.5330	21 CFR 882.5330	21 CFR 882.5320 21 CFR 882.5250 21 CFR 882.5360	21 CFR 872.4120 21 CFR 892.2050	21 CFR 892.2050	21 CFR 888.3080

Characteristic / Name of the device	Subject device <b>TECHFIT Patient-Specific Cranial Implants System</b>	Predicate device <b>Synthes Patient Specific Cranial/Craniofacial Implant</b>	Reference device # 1 <b>OsteoFab™ Patient Specific Cranial Device</b>	Reference device # 2 <b>LeFort Neuro, System Bone Plate &amp; Screw</b>	Reference device # 3 <b>TECHFIT DISRP® System</b>	Reference device # 4 <b>TECHFIT Diagnostic Models</b>	Reference device # 5 <b>ANATOMIC PEEK™ Cervical Fusion System</b>
Fixation method	The implant is attached to the bone with FDA cleared commercially available screw or plates systems.	The implants are attached to the bone using standard Synthes cranial and craniofacial plates and screws in sizes 1.3 mm through 2.0 mm.	The OPSCD is attached to native bone with commercially available cranioplasty fixation system	Screws	NA	NA	The ANATOMIC PEEK devices must be used with supplemental fixation.
Material(s)	Polyether Ether Ketone (PEEK) ASTM F2026	CP Titanium or PEEK	OXPEKK	Plates - CP Ti Gr 1,2,3, and 4 (ASTM F7) Screw – Ti 6Al4V ELI (ASTM F136)	Resin Orthognathic Surgical guides: Biomed Clear Resin. Machined Orthognathic Surgical Guides: CP Titanium. Metal sleeves: CP Titanium	Clear Resin	Polyether Ether Ketone (PEEK)
Manufacturer	TECHFIT Digital Surgery, Inc.	Synthes USA	Oxford Performance Material, LLC	Jeil Medical Corporation	TECHFIT Digital Surgery, Inc.	TECHFIT Digital Surgery, Inc.	Medtronic Sofamor Danek USA
Target population	Adults and adolescents from 18 years old.	Adults	Adults	Adults	Adults	Adults	Adults

<b>Characteristic / Name of the device</b>	<b>Subject device TECHFIT Patient-Specific Cranial Implants System</b>	<b>Predicate device Synthes Patient Specific Cranial/Craniofacial Implant</b>	<b>Reference device # 1 OsteoFab™ Patient Specific Cranial Device</b>	<b>Reference device # 2 LeForte Neuro, System Bone Plate &amp; Screw</b>	<b>Reference device # 3 TECHFIT DISRP® System</b>	<b>Reference device # 4 TECHFIT Diagnostic Models</b>	<b>Reference device # 5 ANATOMIC PEEK™ Cervical Fusion System</b>
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile	Non-sterile	Non-sterile (Steam)	NA	Sterile
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	Custom sized to each patient utilizing CT data	No	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
Manufacturing method	Machining	Machining	3D printing laser sintering process	Machining	3D printing Machining	Additive Manufacturing	Machining
Anatomical sites	Cranial skeleton	Cranial/craniofacial skeleton	Cranial skeleton	Cranial/craniofacial skeleton	Maxillofacial	Maxillofacial	Cervical spine
Device characteristics	PEEK implant is 3.0 mm thick (nominal)	Titanium implant is 2.5 mm thick (nominal) PEEK implant is 3.0 mm thick (nominal).	Thickness 1mm, 2mm, 4mm and release criteria for 3.2mm thickness	Plate thickness 0.3mm~ 1.0mm Screw Outer Dia. 1.4~1.8mm Screw Length 2.2~5.0mm	Software for case management and surgery planning	Diagnostic Models in clear resin	PEEK implant
Implant configuration	Single or multi-piece	Single or multi-piece	Not publicly available	Plates and screws	NA	NA	Single
Compatible with DISRP software?	Yes	NA	NA	NA	Yes	Yes	NA

### 3. Performance data

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

- **Performance Data**

Table 12. Overview of the Performance Data on the Subject Device

Name	Test method	Conclusion
Accuracy Testing	Scanning of a cranial plate and then comparing them versus the existing files	The manufacturing process did not affect the dimensional accuracy of the patient-specific cranial implants by TECHFIT Digital Surgery. These results indicate that our PEEK implants are fabricated with high accuracy independently of their shape and dimensions. The devices showed elevated consistency regarding the original design being truthful to the patient's anatomy.
Compatibility testing	Verifying compatibility between TECHFIT Patient-Specific Cranial Implants manufactured from PEEK (referred to below as TECHFIT Cranial Implants) and the JEIL Le Forte Neuro Plating System 0.6 - K141452 (referred to below as JEIL System).	The JEIL Le Forte Neuro Plating System 0.6 (K141452) is compatible with TECHFIT Patient-Specific Cranial Implants. Therefore, plates and screws from the Jeil Neuro Plating System 0.6 can be used for attaching TECHFIT Cranial Implants to the skull.
Adjustment test	Evaluate the proper adjustment of TECHFIT Patient-Specific Cranial Implants to the bone utilizing an anatomic model of the patient's cranial defect	TECHFIT Patient-Specific Cranial Implants allow a unique adjustment position to the patient's bone.
Software testing	Verifying the item parts for the software	The verification and validation components of the software have been thoroughly tested.
Mechanical testing	To evaluate the static tensile strength of TECHFIT Patient-Specific Cranial Implants	All specimens experienced elastic deformation within the narrow section
Mechanical testing	To test the static four point bending strength and verify the mechanical behavior of TECHFIT Patient-Specific Cranial Implants, manufactured from PEEK.	Testing was terminated after the construct failed to maintain load. Screws pulled from PEEK blocks more abruptly than other specimens

Mechanical testing	To test the static four point bending strength and verify the mechanical behavior of JEIL System plate fixated to Sawbones bone foam.	Testing was terminated after the construct failed to maintain load and the plate yielded. Rough graph curves after a certain displacement likely an artifact of the bone foam yielding as shear load is allied to the screws within the fragments.
Mechanical testing	To test the static four point bending strength of the provided PEEK blocks.	Failure mode for all static test specimens was plastic deformation due to positive bending moment.

- Biocompatibility Testing

Table 13 presents an overview of the tests conducted with the subject device.

Table 13. 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
Hemolysis (ISO 10993-4)	No hemolysis effect
Acute systemic toxicity (ISO 10993-11)	No evidence of systemic toxicity
Material-Mediated Pyrogenicity (ISO 10993-11)	No pyrogenic properties
Chemical Characterization and risk assessment: ISO 10993-18 and ISO 10993-17	Non-toxic
Subchronic systemic toxicity (ISO 10993-11)	Supported by chemical characterization and toxicological risk assessment
Chronic systemic toxicity (ISO 10993-11)	Supported by chemical characterization and toxicological risk assessment
Genotoxicity (ISO 10993-3)	Supported by chemical characterization and toxicological risk

	assessment
Carcinogenicity (ISO 10993-3)	Supported by chemical characterization and toxicological risk assessment
Implantation (ISO 10993-6)	Equivalent physical-chemical characterization of subject and reference device
Neurotoxicity (ASTM F2901-19)	Non- neurotoxicity

#### 4. Conclusion

Non-clinical tests demonstrate that the TECHFIT Patient-Specific Cranial system is substantially equivalent to the predicate device.