August 4, 2022

CenterMed, Inc.
Jash Bhayani
Chief Operating Officer
226 N Wiget Ln
Walnut Creek, California 94598

Re: K211614
Trade/Device Name: CenterMed Patient Matched Assisted Surgical Planning (ASP) System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF, LLZ
Dated: July 29, 2022
Received: August 1, 2022

Dear Mr. Bhayani:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211614

Device Name
CenterMed Patient Matched Assisted Surgical Planning (ASP) System

Indications for Use *(Describe)*

CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP system and the result is an output data file. This file 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 of the Fibula and Ilium, surgical guides for harvesting bone grafts from the Fibula or Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. CenterMed Patient Matched ASP System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

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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510(k) Summary

Submitter Information

Submitter:	CenterMed, Inc.
Submitter Address:	226 N Wiget Ln, Walnut Creek, CA 94598
Contact Person:	Jash Bhayani
Contact Title:	Chief Operating Officer
Phone number:	855-840-8823
E-mail address:	Jash.bhayani@CenterMed.com
Date Prepared:	July 29, 2022 The content is prepared based on the requirements of 21 CFR 807.92

Submission Information

Trade Name:	CenterMed Patient Matched Assisted Surgical Planning (ASP) System
Common Name:	System for the creation of patient specific anatomical models, surgical guides and surgical planning case reports
Classification Name:	Orthopedic Surgical Planning and Instrument Guides (21 CFR 888.3030) (Primary) System, Image Processing, Radiological (21 CFR 892.2050)
Regulatory Class:	Class II
Product Code:	PBF, LLZ
Predicate Device:	KLS Martin Individual Patient Solutions (IPS) Planning System (K192979)
Device Description:	CenterMed Patient Matched Assisted Surgical Planning (ASP) System is a combination of software design and additive manufacturing for customized virtual pre-surgical treatment planning in Maxillofacial reconstructive surgeries. The system processes patients' imaging data files obtained from the surgeons for treatment planning and outputs various patient-specific products (both physical and digital), including surgical guides for harvesting bone grafts from the Fibula or Ilium, anatomical models of the Fibula and Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. The physical products (surgical guides, anatomical models) are manufactured with biocompatible polyamide (PA-12) using additive manufacturing (Selective Laser Sintering).

Indications for Use: CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP system and the result is an output data file. This file 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 of the Fibula and Ilium, surgical guides for harvesting bone grafts from the Fibula or Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. CenterMed Patient Matched ASP System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

1 Abbreviations

Abbreviation	Definition
ASP	Assisted Surgical Planning
COTS	Commercially off-the-shelf
CT	Computer Tomography
DICOM	File Format; Digital Imaging and Communications in Medicine
IPS	Individual Patient Solutions
PA-12	Polyamide 12
SAL	Sterility Assurance Level
SLA	Stereolithography
SLS	Selective Laser Sintering
STL	File format used in 3D printing

2 General Workflow

The general workflow of CenterMed Patient Matched Assisted Surgical Planning System begins with software simulation of patients' imaging data files obtained from the surgeon for treatment planning. Products (surgical guides and anatomical models) are designed and approved by the surgeon based on these imaging data files and converted to 3D STL files. Simultaneously, a surgical planning case report is created based on the same imaging data files as well as the STLs of the designed products. Receiving signed approval from the surgeon, the STL files of the product are sent to manufacturing to be pre-processed, 3D-printed, and post-processed. The completed output of the system includes the surgical planning case report, anatomical models, and corresponding surgical guides. These are packaged, labeled, and sent to the surgeon clean and non-sterile. The surgeon or relevant hospital staff will sterilize the surgical guides and anatomical models before use in the operating room. The workflow is shown in Figure 1.

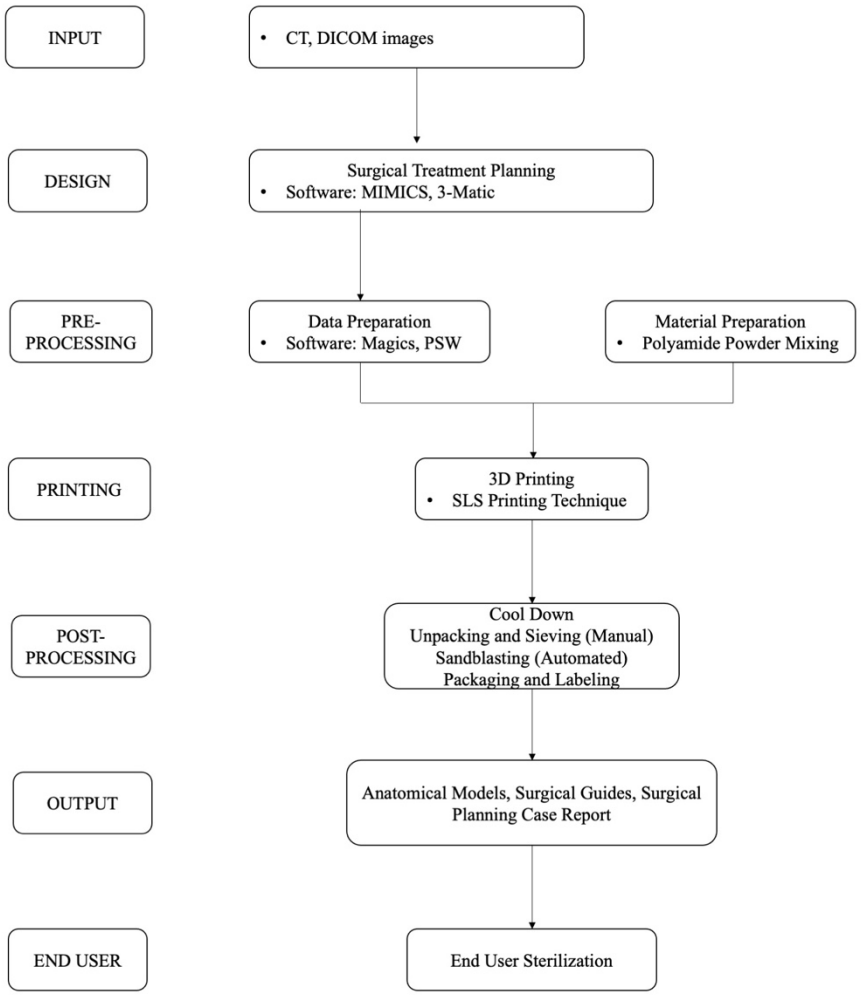

Figure 1: General Workflow of CenterMed Patient Matched ASP System

3 Technological Characteristics / Substantial Equivalence Discussion

Both the subject device and predicate device have similar indications for use.

Indications for use of the subject device

CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP 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 of the Fibula and Ilium, surgical guides for harvesting bone grafts from the Fibula or Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. The subject device and predicate device are also both intended as a pre-operative software tool for simulating/ evaluating surgical treatment options.

Indications for use of the predicate device:

The KLS Marin 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 in an additive manufacturing portion of the system that produces physical outputs including anatomical models, guides and case reports for use in thoracic (excluding spine) and reconstructive surgeries. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

4 Similarities to Predicate

Both the subject device and predicate device fit the same premarket regulation and are identical in conditions of use.

Both the subject device and predicate device share the same fundamental technologies. They both use a combination of software and hardware. Commercially off-the-shelf (COTS) software systems are used for image transfer, manipulation, surgical simulation as well as digital model creation of patient specific anatomical models, and surgical guides. These software systems are intended to be operated by well-trained engineers and the outputs are evaluated by physicians. The additive manufacturing hardware is used to manufacture the physical models from the digital models.

Both the subject device and predicate device share the same fundamental technologies as follows:

- Both use medical imaging data, such as CT scans, in DICOM format as input data file;
- Both have the same system outputs, including anatomical models, and surgical guides;

- Both generate digital models and surgical planning case reports to assist physicians in how to use the products during clinical operation;
- Both use the same materials for surgical guides (Polyamide-12);
- Both use additive manufacturing techniques for product manufacturing;
- Both use the same manufacturing methods for printing surgical guides (Selective Laser Sintering (SLS));
- Both are passive medical devices;
- Both are patient-specific devices;
- Both are provided for single-use;
- Both are provided non-sterile with an end-user sterilization method of steam sterilization with the validated assurance level of 10^{-6} SAL;
- Both use temporary screws for surgical guide fixation to temporarily fix the surgical guide to the target bone surface for more precise guidance of the osteotomy position;
- Both devices require trained employees/engineers who utilize the software applications to manage data and work with the physician to create the virtual surgical plan;
- Both devices need the physician to provide input for surgical planning and give feedback of the system outputs by viewing digital models modified by trained employees/engineers during the planning session.

5 Differences from Predicate

- The predicate device indicates the thoracic region in their indications for use which is not present in the subject device. The subject device is indicated for the fibula and ilium regions of the body.
- Subject device creates anatomical models using Polyamide-12 (PA-12) material with a SLS manufacturing process, whereas the predicate device uses resin material with an SLA manufacturing process.
- For the predicate device, manufacturing materials include epoxy/resin and acrylic for anatomical models, and polyamide, Titanium Alloy (Ti-6Al-4V) and CP Titanium for guides. The subject device only uses PA-12 to manufacture all anatomical models, and surgical guides.
- The predicate device provides two kinds of surgical guides, one made with polyamide and the other made with Titanium Alloy (Ti-6Al-4V) and CP Titanium. The subject device only uses surgical guides made of polyamide, along with medical grade 316L stainless steel sleeves.

- The predicate device uses previously cleared fixation screws which range from 2.3mm – 3.2mm diameter, with length of 7mm - 17mm. The subject device recommends a range of standard screw sizes to the doctor (diameter 1.5mm – 2.1mm, length 5mm - 22mm) (Standard screw sizes determined by manufacturer catalogs of medical grade screws for maxillofacial surgeries).
- Both the predicate and subject device utilize Materialise Mimics for image segmentation and processing, but the predicate and subject device use different additional commercially off-the-shelf (COTS) software applications for image segmentation and processing. Additionally, the subject device utilizes two (2) commercially off-the-shelf (COTS) software for manufacturing.
- The predicate device has one contraindication that is not present in the subject device, "Bone tumors located in the implant base region". The subject device does not include implants and therefore this contraindication is not relevant to the subject device. All other contraindications are identical to the predicate device.

Table 1: Subject and Predicate Device Comparison

Characteristics	Subject Device	Predicate Device
	CenterMed Patient Matched Assisted Surgical Planning (ASP) System	**KLS Martin IPS Planning System (K192979)**
Product Code	LLZ, PBF	LLZ, PBF
Classification	21 CFR 892.2050, Class II 21 CFR 888.3030, Class II	21 CFR 892.2050, Class II 21 CFR 888.3030, Class II
Common Name	System for the creation of patient specific anatomical models, surgical guides and surgical planning case reports	System for the creation of patient specific anatomical models, cutting/marking guides, and case reports
Indications for use	CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP system and the result is an output data file. This file 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 of the Fibula and Ilium, surgical guides for harvesting bone grafts from the Fibula or Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. CenterMed Patient Matched ASP 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 in an additive manufacturing portion of the system that produces physical outputs including anatomical models, guides, and case reports for use in thoracic (excluding spine) and reconstructive surgeries. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

Contraindications	1. Active infections (obvious, or clinically apparent). 2. Hypersensitivity to foreign bodies. 3. Circulatory problems, systematic diseases, or metabolic disorders. 4. Insufficient or inadequate bone tissue. 5. Secondary diseases such as degenerative processes that may have negative influences. 6. Interventions carried out in a non-sterile environment 7. Regions exposed to inappropriate forces or excessive weight loads 8. Patients unwilling to follow instructions during the postoperative phase due to their mental, neurological, or physical condition. 9. Obvious drug or alcohol abuse 10. Significant changes to the patient's anatomy have occurred since the medical scan used for planning purposes was obtained.	1. Obvious infections. 2. Hypersensitivity to foreign bodies. 3. Circulatory problems, systemic diseases, and metabolic disorders. 4. Insufficient or inadequate bone tissue. 5. Secondary diseases such as degenerative processes that may negatively influence the healing process. 6. Interventions carried out in a non-sterile environment. 7. Regions exposed to inappropriate forces or excessive weight loads. 8. Patients unwilling or unable to follow instructions during the postoperative phase due to their mental, neurological, or physical condition. 9. Bone tumors located in the implant base region. 10. Obvious drug or alcohol abuse. 11. Significant changes to the patient's anatomy has occurred since the medical scan used for planning purposes was obtained.
Clinical Application	Maxillofacial reconstructive surgeries	Thoracic (excluding spine) and reconstructive surgeries
Prescription Use	Yes, intended to be used by physicians, not for use by patients.	Yes, intended to be used by physicians, not for use by patients.
Energy used/delivered	Passive	Passive
System Inputs	CT, DICOM images,	CT, DICOM images
System Outputs	Anatomical models, Surgical guides, Surgical planning case reports	Anatomical models, Guides, Case reports
Materials	Anatomical models: Medical Grade Polyamide (PA-12)	Anatomical models: Epoxy/Resin, Acrylic

	Surgical guides: 3D printed part: Medical Grade polyamide (PA-12) Sleeve: Medical Grade Stainless Steel 316L	Cutting/Marking guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium
Manufacturing Method	Medical Grade Polyamide (PA-12): 3D (Additive; Selective Laser Sintering (SLS)) Medical Grade Stainless Steel 316L: Traditional (Subtractive)	Epoxy/Resin, Acrylic: 3D (Additive; Stereolithography (SLA)) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting) Polyamide: 3D (Additive; Selective Laser Sintering)
Patient-specific configuration?	Yes	Yes
Provided for single-use?	Yes	Yes
Provide sterile?	No	No
Sterilization Method	Steam Sterilization	Steam Sterilization
Recommended Temporary Screw Diameter	1.5mm-2.1mm	2.3mm – 3.2mm
Recommended Temporary Screw Length	5mm-22mm	7mm -17 mm
Recommended Temporary Screw Style	Drill-Free, Tapping-Free	MaxDrive (Drill-Free, non-locking, locking)

6 Device Types and Functions

Table 2 lays out the types, materials, and functions of the various devices offered in the CenterMed Patient Matched ASP System.

Table 2: Types and Functions of CenterMed Patient Matched Devices

Category	Material	Function
Anatomical Models	• PA-12	• Visual representation of patient's bone pre and/or post-op
Cutting Guide	• PA-12 • 316L Stainless Steel	• Cutting reconstructive bone

7 Non-clinical Performance Data

The following non-clinical performance testing was performed as supportive evidence to demonstrate substantial equivalence:

- Mechanical testing
- Dimensional testing
- Wear debris testing
- Biocompatibility testing
- Sterilization testing
- Software validation

Table 3 shows an overview of the testing performed on surgical guides, and validation testing performed on the COTS software.

Table 3: Summary of Non-Clinical Performance Data

Test performed	Test description/Guidelines	Conclusion	Safety and Efficacy Confirmed
Mechanical testing	ISO 178:2019	The results showed that the sterilized and aged test specimens met the pre-defined acceptance criteria: maintain 85% of initial bending strength. The test specimens used for bending testing were designed and	Yes

		tested according to these ISO standards.	
	ISO 20753:2018	The smaller test specimens used for tensile testing were designed according to this ISO standard.	Yes
	ASTM D638	The larger test specimens used for tensile testing were designed according to this ASTM standard.	Yes
	ISO 527-2:2012	The results showed that the sterilized and aged test specimens can reach the pre-defined criteria: maintain 85% of initial tensile strength.	Yes
Dimensional testing	Pre-defined dimensional tolerance limits	The results showed that the dimensional changes were within the predefined acceptance criteria.	Yes
Wear debris testing	Pre-defined average amount of material loss	The results showed that the average material loss was within the predefined acceptance criteria.	Yes
Cytotoxicity	ISO 10993-5, GB/T 16886.5-2017	The results showed no evidence of the test specimen causing cell lysis or toxicity.	Yes
Sensitization	ISO 10993-10, GB/T 16886.10-2017	The test specimen extracts showed no evidence of causing delayed dermal contact sensitization.	Yes
Intracutaneous reactivity	ISO 10993-10, GB/T 16886.10-2017	The results showed no evidence of intra-cutaneous reactivity.	Yes
Acute Systemic toxicity	ISO 10993-11, GB/T 16886.11 2011	The results showed no mortality or evidence of systemic toxicity.	Yes

Pyrogenicity	USP <151>, ISO 10993-11	The results met the requirements for the absence of pyrogens.	Yes
Sterilization validation	ANSI/AAMI/ISO 17665-1	The results demonstrated the assurance of sterility of 10^{-6} SAL (sterility assurance level) for surgical guides and anatomical models individually packaged in a single-pouched or wrapped sterilization configuration.	Yes
Software validation	Pre-defined requirement specifications	All the COTS software applications for image segmentation and manipulation are FDA cleared. Quality and on-site user acceptance testing provide objective evidence that all software requirements and specifications were implemented correctly and completely and are traceable to the system requirements. Testing required as a result of risk analysis (level of concern) and impact assessments showed conformity with pre-defined specifications and acceptance criteria. Software documentation demonstrates all appropriate steps have been taken to ensure mitigation of any potential risks and the system performs as intended based on the user requirements and specifications.	Yes

8 Clinical Performance Data

Clinical testing was not necessary for the determination of substantial equivalence, or safety and effectiveness of the CenterMed ASP System. The predicate device did not perform clinical testing for their products (surgical guides, anatomical models, case reports), and since there are no significant technological differences, or significant indications for use differences between the subject device products (surgical guides, anatomical models, surgical planning case reports) and the predicate device, clinical testing is not needed for the subject device.

9 Animal Studies Data

Animal testing was not necessary for the determination of substantial equivalence, or safety and effectiveness of the CenterMed ASP System. The predicate device did not perform animal testing for their products (surgical guides, anatomical models, case reports), and since there are no significant technological differences, or significant indications for use differences between the subject device products (surgical guides, anatomical models, surgical planning case reports) and the predicate device, animal testing is not needed for the subject device.

10 Conclusions

The predicate device chosen was KLS Martin Individual Patient Solutions System. It was shown that the subject device, CenterMed Patient-Matched Assisted Surgical Planning System is substantially equivalent to the predicate device. Both have the same indications for use as a software and image segmentation system for the transfer of imaging information from a medical scanner, and both result in creation of outputs such as anatomical models, surgical guides, and surgical planning case reports for use in reconstructive surgery. Both create physical outputs using rapid prototyping. They are both intended for use as a pre-operative software tool for simulating and evaluating surgical treatment options.

Any differences between the predicate device and the subject device have been thoroughly analyzed to conclude no safety or efficacy issues in the subject device. A full risk analysis was performed to determine the safety of the device, and any residual risk has been justified. Additionally, mechanical, biocompatibility, and sterilization tests have been performed to analyze the safety and effectiveness of the subject device. All tests passed their respective test criteria. Software risk analysis and validation was also performed to confirm the safety and effectiveness of the COTS software used to design and manufacture the subject device.

Based on the comparisons and analyses detailed above in this summary, we believe that the information and performance test reports of the subject device provided in this 510(k) submission are sufficient to demonstrate the safety and effectiveness of the CenterMed Patient Matched ASP System. Additionally, the information and performance test reports provided support the conclusion of Substantial Equivalence to the predicate device.