Journey to a 510(k) Clearance for a Point-of-Care Additive Manufacturing Facility

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Disclaimer

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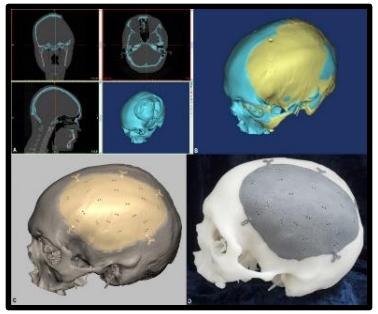
Nikki McMinn, MME has disclosed no relevant, real, or apparent personal or professional financial relationships with proprietary entities that produce healthcare goods and services.

Presentation Outline

1. Beginning the Journey (Acquisition of Funding and QMS Implementation)
2. Continuing the Journey (Product Development Phases and Testing)
3. Completing the Journey (Submission and Clearance of the 510(k)!)
4. Overall Pros and Cons (Throughout Presentation)

Staff and Production

- Team of 7
  - Director of Services
  - Engineers (Biomedical and Quality)
  - Technicians (Engineering and Dental)
  - Administrator
- Production since 2003:
  - Medical models and devices
  - Thousands of requests per year
  - Over 100 custom unique prosthetic and rehabilitation devices and attachments
  - Research, simulation, and training models



3-D Medical Applications Center (3-D MAC)

The 3-D Medical Applications Center (3-D MAC) is an Additive Manufacturing Facility located within the Department of Radiology at WRNMMC.

The mission of the 3-D Medical Applications Center is to provide:

- Digital support and fabrication of medical models, custom implants, surgical guides, and custom devices
- Technical support for virtual treatment planning
- Image capture/3-D scanning for patient treatment
- Input as an active participant in graduate medical/dental education and research

Learn about our:

- 3-D Technology
- 3-D Scanning Guidelines
- 3-D Printing Applications

We serve WRNMMC, the Uniform Services University of the Health Sciences, the Naval Postgraduate Dental School, DoD military and dental treatment facilities, other federal entities, and worldwide allied medical institutions. Please watch the 3-D MAC Video below to learn more.

Place an Order (CAC Required)

Contact Us

Hours
Monday- Friday
0700 - 1600

Phone
(301) 295-8594

Email
dha.bethesda.walter-reed-med-ctr.list.wrnm-3dmac@health.mil

Location
3D Medical Applications Center
8901 Rockville Pike
Building 1, 4th Floor, Room 4426
Bethesda, MD 20889

Place an Order
Place an Order (CAC Required)

https://walterreed.tricare.mil/About-Us/Facilities/3-D-Medical-Application-Center-3-D-MAC

*Technology videos are online

Initial Steps: Where It All Began

Funding Sources and QMS Development

Funding Acquisition

- Joint Incentive Fund (JIF) priorities:
  - Improved Access to Care
  - Improved Quality of Care
  - VA / DoW Joint Strategic Partnership and Innovation
  - Optimization of Telemedicine Capabilities
  - ROI / Cost Savings
  - DoW Readiness / Graduate Medical Education

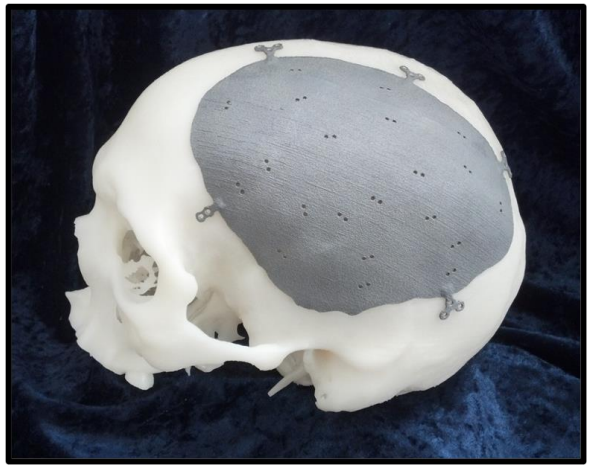
- JIF for Fiscal Year 2020 was secured between 3D MAC and Veterans Health Administration at Puget Sound

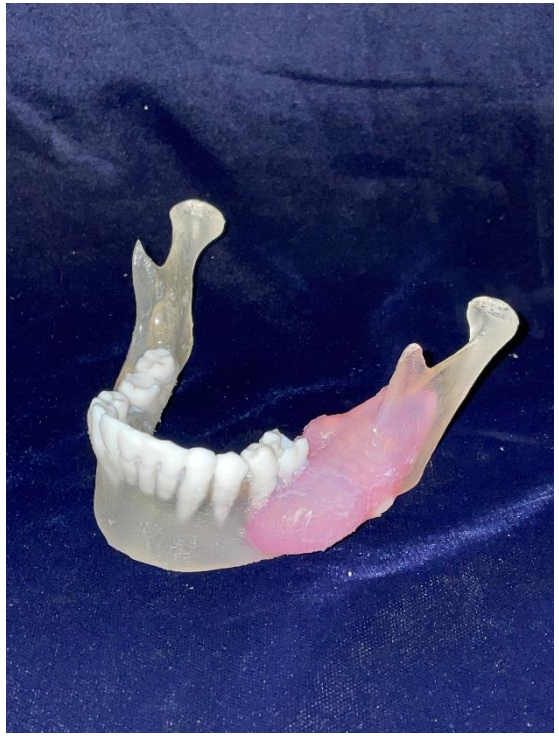
DoW/VA 3D Printing Consortium for Medical Applications

- Develop DoW/VA quality standard for 3D printing in healthcare per FDA and ISO standards
- Augment 3D printing capabilities and capacity
- Develop interagency training and workforce development program

Implementing a QMS at the Point-of-Care

- Expensive and time-consuming
- Proposed FDA PoC scenarios
- Prepare for future FDA regulations for Point-of-Care Facilities
- Pick your product/device





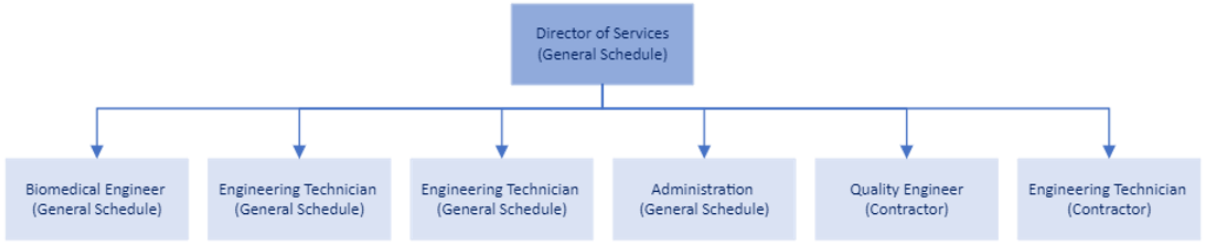
Starting Point: Quality Manual And Plan

- Will change over the implementation of your QMS
- Great “table of contents” to demonstrate meeting FDA and ISO regulations

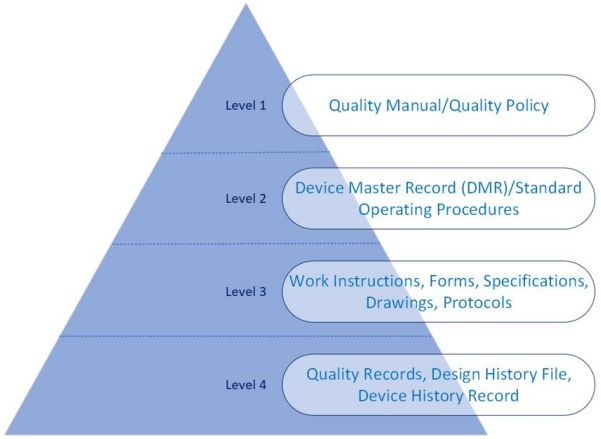
Inclusions and Exclusions, 3D MAC is using a Risk Based Approach

Product	Associated Risk
Cranial Plates	High
Metal Dental Components	Medium
Prosthetic Components	Low
Anatomical Models (including Dental Models)	Excluded

8.6.1.2 The organizational chart for 3D MAC is as follows:



Documentation Hierarchy



3D MAC QUALITY POLICY:

Quality is the cornerstone of our patients’ experience. Through regulatory compliant systems, a maintained quality management system, and continuous improvement we provide products and services to improve the quality of life of those we are privileged to serve.

3D MAC QUALITY OBJECTIVES

- **Gather actionable data and develop meaningful key performance indicators**
- **Obtain zero product escapes in 2023**
- **Training for all Engineers in ISO 13485 and 21 CFR Part 820 by 2024**
- **Have zero safety incidents in the workplace and zero product recalls**
- **Implement the quality management system for all relevant product types**

How Plan Fulfills Requirements

21 CFR Part 820	ISO 13485	3D MAC Documents
§820.1 Scope	1 Scope	00-001 3D MAC Quality Manual
	2 Normative References	
§820.3 Definitions	3 Terms and Definitions	
§820.5 Quality System	4 Quality Management System	
	4.1 General Requirements	
	4.2 Documentation Requirements	01-001 SOP, Control of Documents and Records
820.20 Management Responsibility	5 Management Responsibility	00-001 3D MAC Quality Manual 01-011 SOP, Management Review
820.20(a) Quality Policy	5.2 Customer Focus 5.3 Quality Policy	00-001 3D MAC Quality Manual
820.20(b) Organization	5 Management Responsibility	
820.20(b)(1) Responsibility & Authority	5.5 Responsibility & Authority	
820.20(b)(2) Resources	5.1 Management Commitment	
820.20(b)(3) Management Representative	5.5.2 Management Representative	
820.20(c) Management Review	5.6 Management Review	01-011 SOP, Management Review
820.20(d) Quality Planning	5.4 Quality Planning	00-001 3D MAC Quality Manual
820.20(e) Quality System Procedures	4.2.1 General	
	4.2.2 Quality Manual	
820.22 Quality Audit	8.2.4 Internal Quality Audits	01-022 SOP, Internal Audits
	8.2.5 Monitoring and Measurement of Processes	01-011 SOP, Management Review 01-022 SOP, Internal Audits
820.25 Personnel	6 Resource Management	00-001 3D MAC Quality Manual
820.25(a) General	6.1 Provision of Resources	

Now for the Fun Part: Product Development Phases

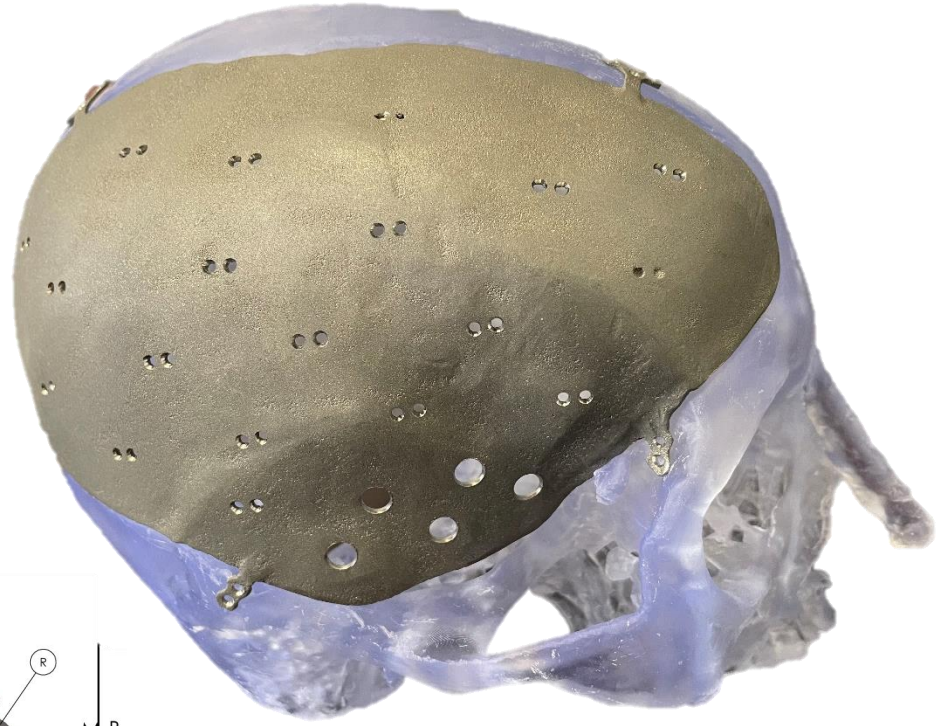
Device, Technologies, and Materials

Product Development Plan

- Phase 1: Investigation and Viability
- Phase 2: Product Planning
- Phase 3: Detailed Development
- Phase 4: Clinical/Regulatory Preparation
- Phase 5: Market Introduction

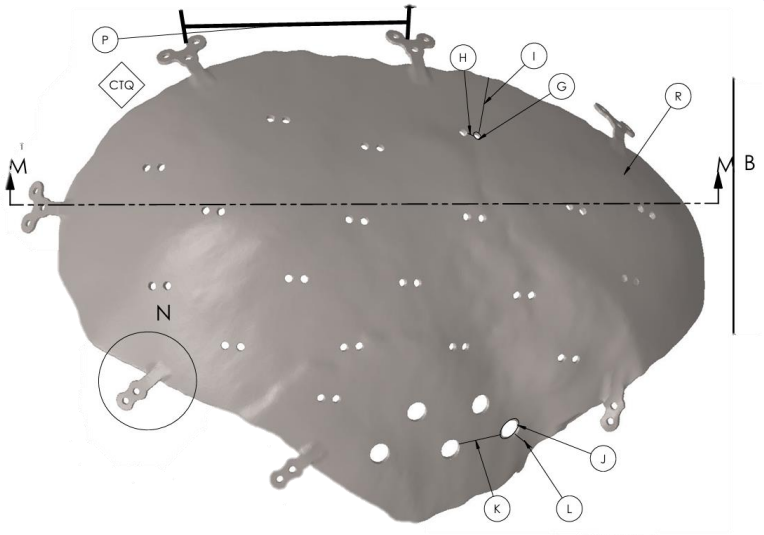
Device Dictates Project

- Our device system includes 2 parts:
  - Titanium Cranial Plate Implant (TCP)
  - Skull Anatomic Model (SAM)



- Intended use: Replacing bony voids in the skull

- Product planning includes:
  - Regulatory and clinical analysis
  - Design and manufacturing
  - Testing needed



Design Envelope and Inspection

DOCUMENT NUMBER:	REVISION LEVEL:	DOCUMENT TYPE:
09-098	02	Form
DOCUMENT TITLE:		
Form, TCP System Final Inspection		

TCP System Final Inspection Form

TCP UDI: _____ SAM UDI: _____

Work Order: _____ Date Inspected: _____

Inspection Equipment Used

8" Calipers: ☐ E-012 ☐ E-013 ☐ E-023 ☐ E-024

Thickness Gage: ☐ E-022 Caliper Gage: ☐ E-018 Pin Gage: ☐ E-010 Granite Surface: ☐ E-016

TCP Implant

Attribute	"Worst" Measured Dimension (mm)	Equipment Used (E-)	Pass/Fail	Comments
Visual Inspection	N/A	N/A	☐ Pass ☐ Fail	
Number of Fixations	N/A	N/A	☐ Pass ☐ Fail	
Edge Roughness	N/A	N/A	☐ Pass ☐ Fail	
Critical Dimensions				
Plate Thickness		E-018	☐ Pass ☐ Fail	
Fixation Thickness		E-022	☐ Pass ☐ Fail	
Screw Hole Diameter	N/A	E-010	☐ Pass ☐ Fail	
Fixation Neck Width			☐ Pass ☐ Fail	
Screw Hole Edge to Edge Distance			☐ Pass ☐ Fail	
Screw Hole to Fixation Edge			☐ Pass ☐ Fail	
Implant Edge to Fixation Edge Distance			☐ Pass ☐ Fail	
Max Linear Distance Between Fixations			☐ Pass ☐ Fail	
Non-Critical Dimensions				
Suture Hole Diameter	N/A	N/A	☐ Pass ☐ Fail	
Suture Hole Pair Edge to Edge Distance	N/A	N/A	☐ Pass ☐ Fail	
Suture Hole to Edge Distance	N/A	N/A	☐ Pass ☐ Fail	
Temporalis Suture Hole Diameter	N/A	N/A	☐ Pass ☐ Fail ☐ N/A	
Temporalis Hole Edge to Edge Distance	N/A	N/A	☐ Pass ☐ Fail ☐ N/A	
Temporalis Hole to Implant Edge Distance	N/A	N/A	☐ Pass ☐ Fail ☐ N/A	

Inspected By: _____ **Date Inspected:** _____

Skull Anatomical Model

Skull Material: ☐ Accura ClearVue ☐ Biomed Clear Fit Test (DIM Q): ☐ Pass ☐ Fail Clearance Check: ☐ Pass ☐ Fail

Dimension (mm):	A	B	C
Expected:			
Measured:			

Inspected By: _____ **Date Inspected:** _____

Labeling Inspected: UDI Verified ☐ Patient Name ☐ Use By Date ☐ Case Report Included ☐ IFU Included ☐

Packaged per WI 02-066: ☐

Packaged and Labelled by: _____ **Date:** _____

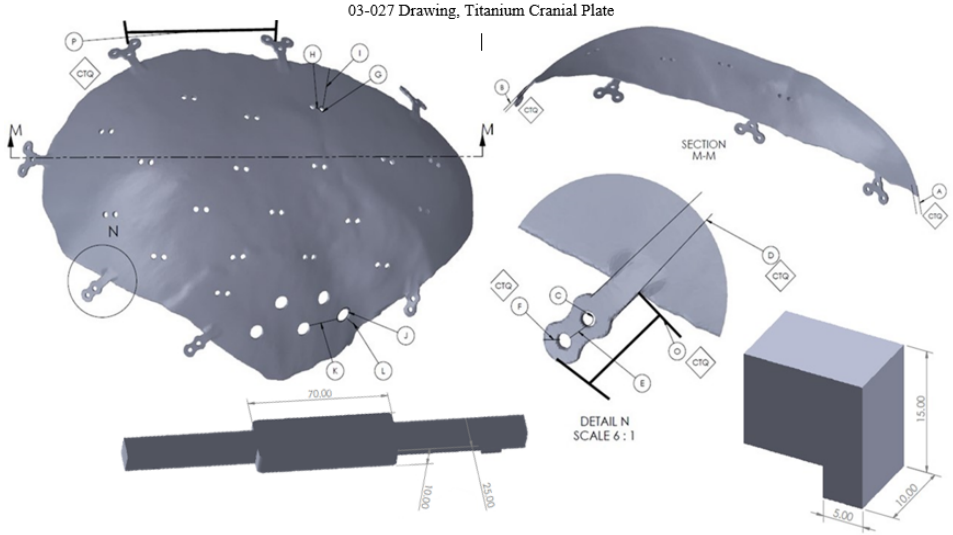
Quality Approval: _____ **Date Approved:** _____

DOCUMENT NUMBER:	REVISION LEVEL:	DOCUMENT TYPE:
09-098	02	Form
DOCUMENT TITLE:		
Form, TCP System Final Inspection		

Acceptance Criteria for TCP System Dimensional Inspection

		Attribute	Dimension (mm)		Equipment Used
Implant Body	A	Plate Thickness	1.5 ± 0.5		Caliper Gauge
Implant Fixations	B	Fixation Thickness	$0.85 \pm {}^{0.15}_{0.10}$		Thickness Gauge
	C	Screw Hole Diameter	Ø1.60 to 2.15		Caliper/ Pin Gauge
	D	Fixation Neck Width	$3.0\,{}_{-0.25}$		Caliper
	E	Screw Hole Edge-to-Edge Distance	$2.0\,{}_{-0.5}$		Caliper
	F	Screw Hole to Fixation Edge Distance	1.5 ± 0.5		Caliper
	O	Implant Edge to Fixation Edge Distance	≤14 mm or ≤12 mm		Caliper
	P	Max Linear Distance Between Fixations	150mm/100 mm		Caliper
Dura Suture Holes	G	Suture Hole Diameter	$Ø1.50 \pm {}^{1.00}_{0.50}$		Caliper/ Pin Gauge
	H	Suture Hole Pair Edge-to-Edge Distance	> 1x Ø of DS hole min		Caliper
	I	Suture Hole-to-Edge Distance	$\geq 5.00\,{}_{-0.00}$		Caliper
Temporalis Suture Holes	J	Temporalis Suture Hole Diameter	Ø 1.5 ±0.5 to 4.5 ±0.5		Caliper/ Pin Gauge
	K	Temporalis Hole Edge to Edge Distance	> 1x Ø of TS hole min		Caliper
	L	Temporalis Hole to Implant Edge Distance	$\geq 5.00\,{}_{-0.00}$		Caliper
SAM Measuring / Labeling Block		Dimension A	5.00 mm	25.00 mm	Caliper
		Dimension B	10.00 mm	70.00 mm	Caliper
		Dimension C	15.00 mm	10.00 mm	Caliper

03-027 Drawing, Titanium Cranial Plate



Master Verification and Validation Plan

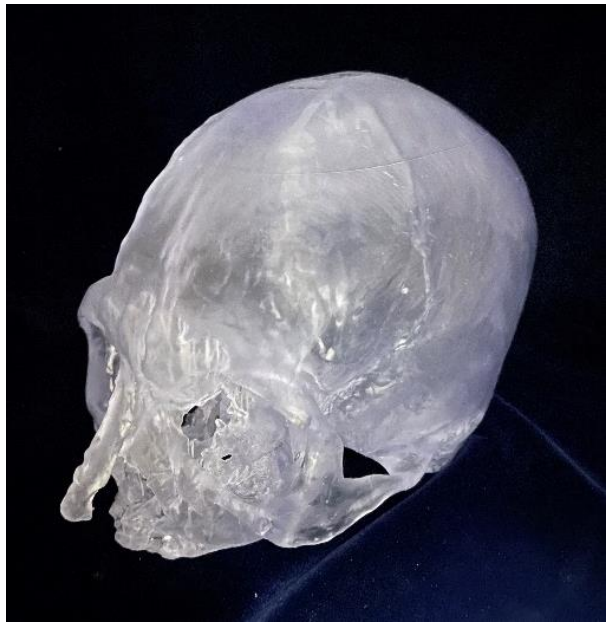
- Overview of the process
  - Case Initiation
  - Segmentation
  - Implant and Model Design
  - Implant and Model Production
  - Implant and Model Post-processing
  - Labeling
  - Shipping and Delivery
  - Cleaning and Sterilization with SPD

Process:	Sub-Process:	Description:	Equipment, Tool, Software, Material, Process:	Verification or Validation:	Verification or Validation Rationale:	Relevant Documentation/Output:
		for medical applications.	ELI, Grade 23			
Anatomical Model Post Processing	Removal of Supports	Equipment necessary for the post-processing of the SLA manufactured skull model.	Tools: Stainless Steel Hand Tools, Scrapers, and Cutters	Verification	The result is 100% verifiable.	Traveler
	Resin Rinsing	Equipment and material necessary for the cleaning of the SLA manufactured skull model.	Equipment: Formlabs Form Wash	Validation	Validation of the machine will ensure critical functions can be performed.	Machine Validation: Installation Qualification Report
			Material: > 99% IPA	Verification	Material selection is 100% verifiable.	Material Usage Log
			Process	Verification	The result is 100% verifiable.	Traveler
		Equipment and material necessary for the cleaning of the SLA manufactured skull model.	Equipment: PostProcess DEMI	Validation	Validation of the machine will ensure critical functions can be performed.	Machine Validation: Installation Qualification Report
			Material:	Verification	Material selection is	Material Usage Log

Equipment Qualifications

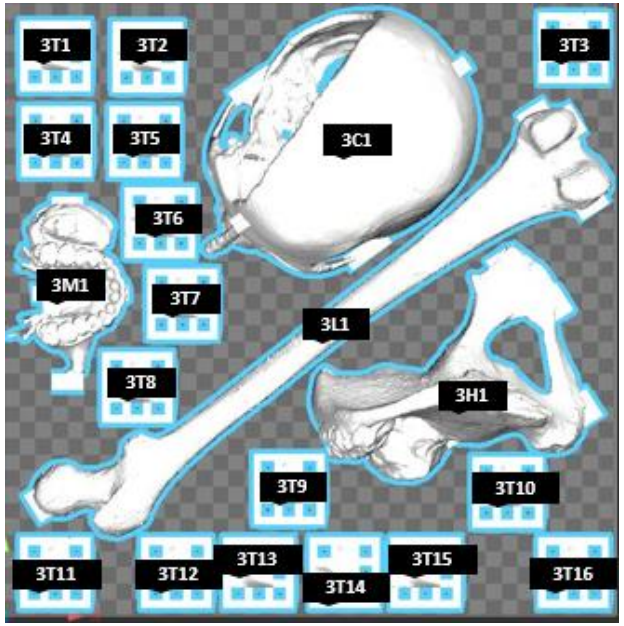
IQ

- Electric power
- Environmental conditions
- Space requirements



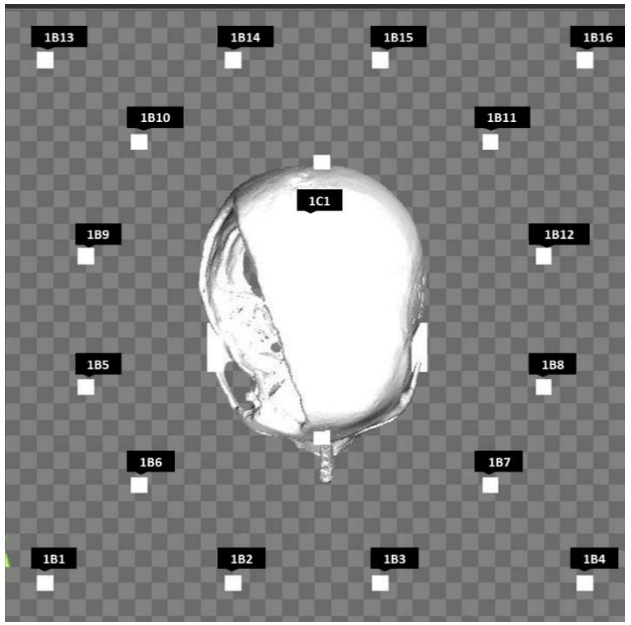
OQ

- Size of parts (min, max)
- Location on platform (edges)
- Part features (thin, thick)



PQ

- Size of parts (medium)
- Location on platform (center)
- Part features (nominal)

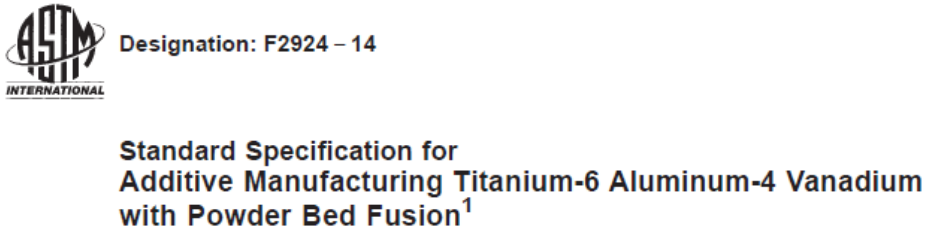


The Long Road: Testing and More Testing

Validation Testing of Medical Device

How to Determine Testing Needed

- Risk of device design, production, use
  - ISO 14971
  - Forces experienced by device
  - Where is device used?
- FDA guidance documents
- FDA's Recognized Consensus Standards


Designation: F2924 – 14

Standard Specification for
Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion[1]


Designation: F3001 – 14

Standard Specification for
Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion[1]


Designation: F543 – 17

Standard Specification and Test Methods for Metallic Medical Bone Screws[1]

Contains Nonbinding Recommendations

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment

Guidance for Industry and Food and Drug Administration Staff

Contains Nonbinding Recommendations

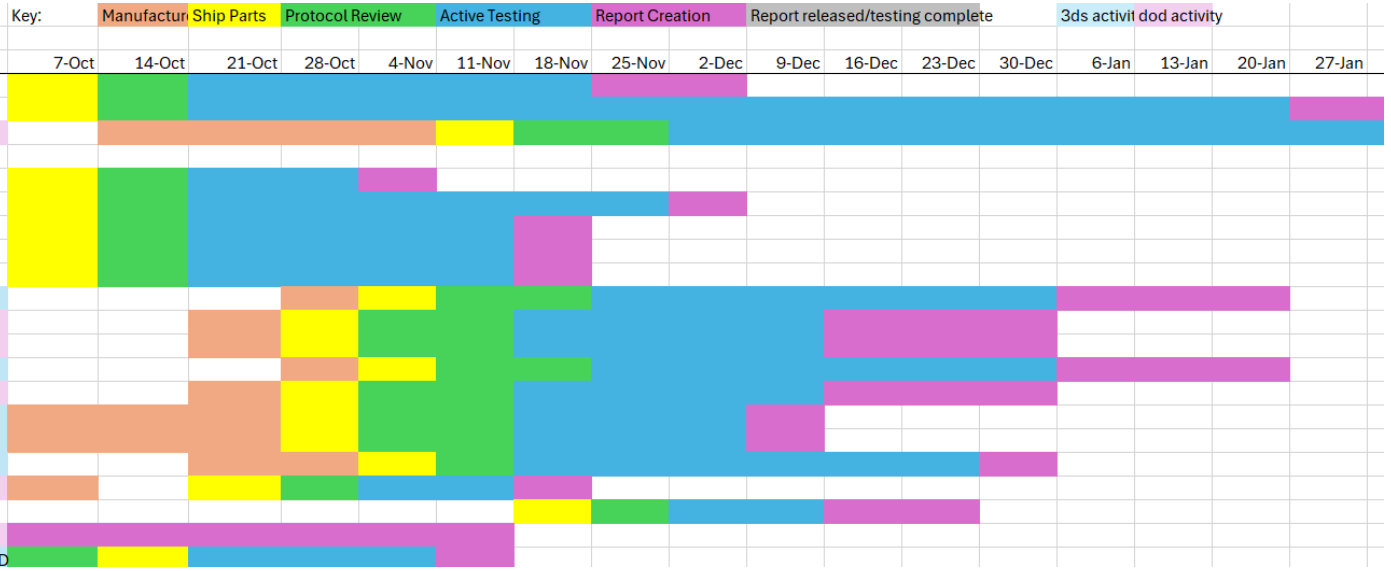
Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Guidance for Industry and Food and Drug Administration Staff

Testing and Timelines

- Map out a timeline for all testing

Test		Coupon	Qty	Next Step
Implantation (4 weeks)		6mm implant	10	wait
Implantation (13 weeks)		6mm implant	12	wait
Extraction		SA plate	30	Manufacture, sterilize, & ship
Toxicology Risk Assessment		Data	NA	Send Extraction Report
Cytotoxicity		30cm SA Disc	1	wait
Sensitization		60cm SA Disc	3	wait
Irritation		30cm SA Disc	2	wait
Systemic Toxicity		30cm SA Disc	3	wait
Pyrogenicity		100cm SA Disc	12	wait
Manual Cleaning (skull)		TBD	~5	Define coupons reqs
Sterilization (skull - accura)		Full Skull	3	Manufacture coupons & ship
Sterilization (skull - biomed)		Full Skull	3	Manufacture coupons & ship
Automated Cleaning (implant)		TBD	~5	Define coupons reqs
Sterilization (implant)		SA plate	3	Manufacture coupons & ship
Dynamic Impact		Mech coupon	6	Send PO, send fixture .step file
Static Compression		Mech coupon	6	Send PO, send fixture .step file
MR Compatibility		SA plate	~1	Define coupons reqs
Implant Manufacturing Capability		Dval implants	3 of each (9)	Shipping parts, scan and analyze.
Shipping and Packaging		DVal Full case	1 of each (3)	Send parts DoD when scanned
Surgeon Usability Validation		DVal Full case	3 of each (9)	Approve final report
Operater Variability Validation (PPQ)		DVal skull STL	3 of each (9)	Analyze variablity send data to DoD



*Warning: Do not expect all testing to comply with the timeline.

Cleaning, Sterilization, and Biocompatibility

- Cleaning validation
- Validation of steam sterilization process
- Biocompatibility testing per ISO 10993
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Acute systemic toxicity
  - Material-medicated pyrogenicity
  - Implantation study
  - Chemical characterization

Sample Considerations

Coupon Design

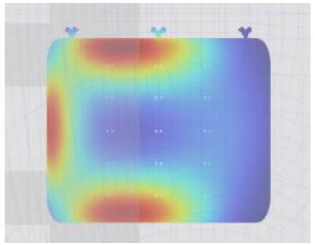
- Specific surface areas outlined in standards
- Designed samples to maximize worst-case features

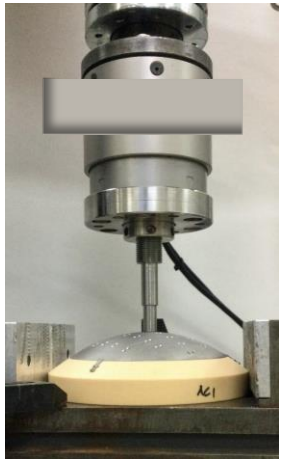
Manufacturing Contact Materials

- Include all potential contact materials in manufacturing coupons

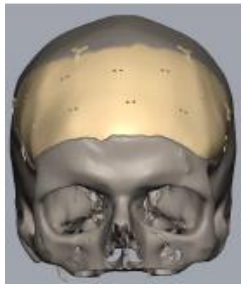
Use and User Validations

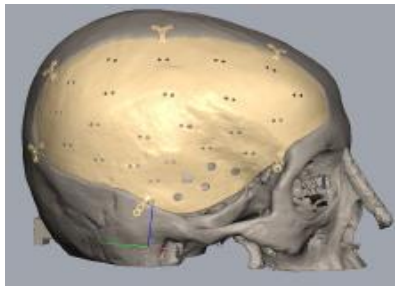
- Physical use testing needed
  - Static and dynamic impact testing
  - MR safety validation

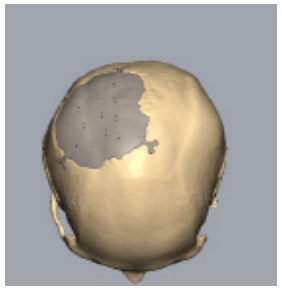




- Design validation with surgeons







	Surgeons		
Engineers	A	B	C
X	Case 1	Case 3	Case 2
Y	Case 2	Case 1	Case 3
Z	Case 3	Case 2	Case 1

Sample Considerations

Coupon Design

- Mechanical testing: Plate with minimum number of fixation points, largest implant surface area
- MR compatibility: Largest metallic mass
- Design validation: Various sizes and design complexity

Manufacturing and Use

- Standard manufacturing process
- Multiple engineers doing the manufacturing
- Multiple surgeons doing all cases

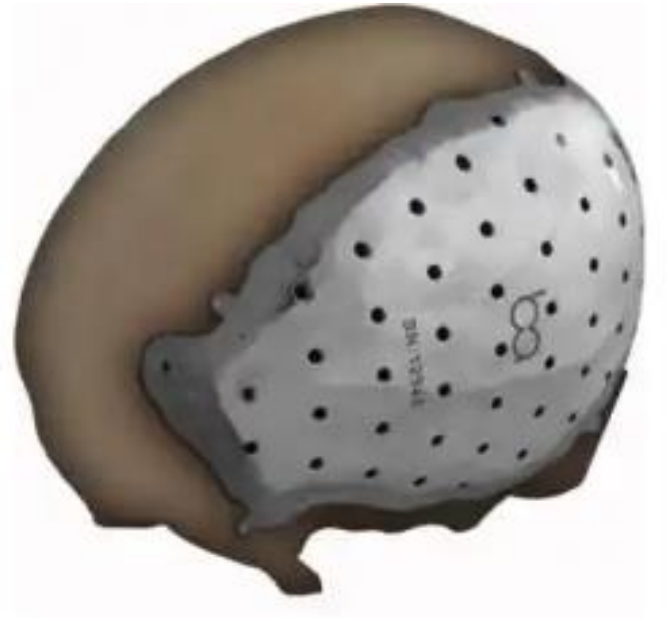
Proving Your Worth: Supporting Substantial Equivalence

Regulatory Submission and Clearance

Regulatory Process

- Class II 510(k) application
  - 882.5330 Preformed nonalterable cranioplasty plate
  - GXN: Preformed nonalterable cranioplasty plate

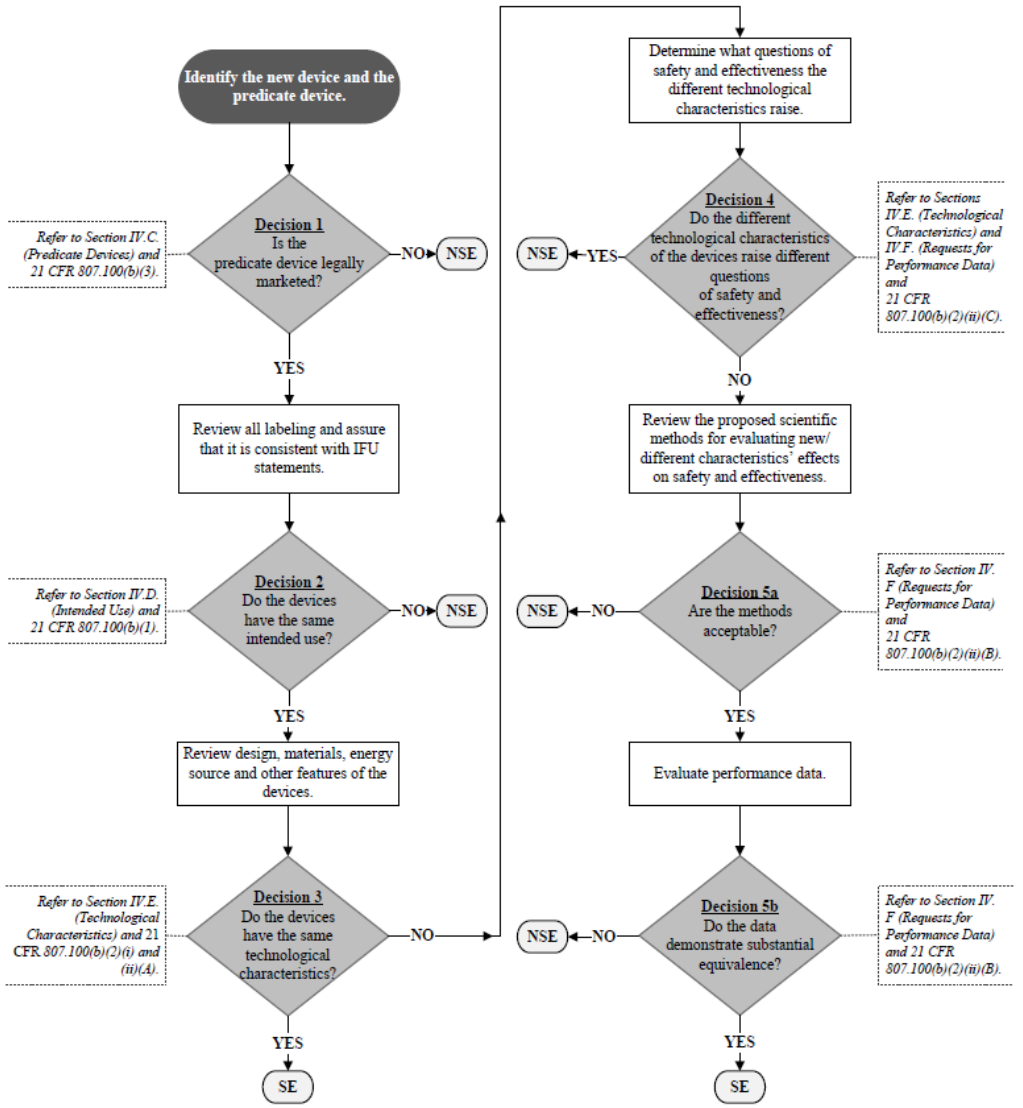
- Substantial equivalence review process
- Predicate selection
  - BioArchitects Patient-Specific Cranial/Craniofacial Plate (K151692)
  - Same intended use and manufacturing method
  - Different design process and mechanical properties



https://3dprint.com/118337/bioarchitects-fda-approval/

510(k) Flowchart and SE Determination

- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]



510(k) eSTAR Submission

- Submitted 510(k): September 24, 2025
- Placed on AI hold: November 21, 2025
- Submitted response to AI letter: May 19, 2026

Progress

Reviewing: We are reviewing this medical device.
Your Reviewer will contact you if we need more information.

Wed Sep 24, 2025
Official start

Tue Dec 23, 2025 | in 75 days
MDUFA decision

Refer to FDA letters for formal descriptions and details.
Future dates are estimates based on MDUFA performance goals.
Day counts exclude days on hold. All records are updated overnight.

- Tue Dec 23, 2025 | in 75 days | Final decision (estimated): We intend to finish our review of this medical device.
- Sun Nov 23, 2025 | in 45 days | Substantive Interaction: We will decide if you can supply us with more information without a hold.
- Oct 8, 2025 | day 14 | We confirmed the material you supplied is complete.
- Sep 24, 2025 | We confirmed your user fee payment.
- Sep 24, 2025 | We confirmed your eCopy/eSTAR.
- Sep 24, 2025 | We received your request to review this medical device.

Service time

15 days since official start, excluding holds

15 total days spent since official start

0 days on hold since official start

75 days left to meet our overall time estimate

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties. ?

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The 3D Medical Applications Center (3D MAC) Titanium Cranial Plate (TCP) System includes (1) a patient-

3D MAC Titanium Cranial Plate (TCP) System Page 10 of 3

specific TCP Implant and (2) a corresponding polymer Skull Anatomical Model (SAM). The 3D MAC TCP System is designed from a patient's imaging to create a patient-specific cranial plate and corresponding SAM. The TCP System is intended to fill bony voids in the cranial and/or craniofacial skeleton. The SAM is provided as a surgical reference tool to aid in the fitting and positioning of the TCP Implant. The TCP Implant is manufactured on an electron beam melting (EBM) 3D printer out of Ti6Al4V titanium alloy powder. The SAM is printed on a stereolithography (SLA) 3D printer out of clear photopolymer resin. The TCP Implant is an implantable, non-load bearing, and non-alterable medical device.

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation ?	
Open Attachment	Section 3.3 A1 TCP Device Description and Principles of Operation.pdf	Delete Attachment
Open Attachment	Section 3.3 A2 Ti6Al4V Powder Certificate of Analysis.pdf	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	Section 3.3 A3 TCP Implant Drawing.pdf	Delete Attachment
Open Attachment	Section 3.3 A4 TCP Skull Anatomical Model Drawing.pdf	Delete Attachment
Add Attachment	Description of Device Packaging ?	
Open Attachment	Section 3.3 A6 TCP System Packaging Protocol.pdf	Delete Attachment
Open Attachment	Section 3.3 A7 TCP System Packaging Validation Report.pdf	Delete Attachment
Open Attachment	Section 3.3 A5 TCP System Packaging Description and Validation.pdf	Delete Attachment

FDA 510(k) Clearance!

Finally!

FDA U.S. FOOD & DRUG ADMINISTRATION

June 18, 2026

The Surgeon General, Department of the Army (TSG-DA)
India El
Regulatory Affairs Scientist

Dear India El:

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

Finally!!!

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"

Challenges for PoC Facilities

People

- Staff considerations/turnover
- Institutional support
- Quality and Regulatory guidance
- **Authority to submit to FDA**

Money

- Funding for project
- Purchasing
- Testing
- Maintenance
- Regulatory submissions
- Material testing

Logistics

- Scope of entire project
- Work instruction creation
- IMT equipment calibration
- Environmental conditions
- Statistical analysis
- Risk documentation

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