

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900		DATE(S) OF INSPECTION 12/16/2025-1/16/2026* FEI NUMBER 1000550978	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Lisa E. Foley, President			
FIRM NAME Marson Medical, Inc.		STREET ADDRESS 64 E Midland Ave	
CITY, STATE, ZIP CODE, COUNTRY Paramus, NJ 07652-2931		TYPE ESTABLISHMENT INSPECTED Contract Manufacturer	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above. <i>The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures. Specifically, your firm failed to implement procedure <i>Validation Process</i> (MAP-0011, Rev B, dated 2/28/2012) to validate orthopedic implant production processes where the results cannot be fully verified with subsequent inspection and test. For example: A. Your firm's validation activities associated with the current and previous ultrasonic cleaning processes fail to provide any assurance your process can operate in a state of control and consistently produces conforming product. Specifically: 1. Your current ultrasonic cleaning process (from approximately 11/11/2024 to present) has no assurance that the cleaning process can consistently produce conforming product that is free from manufacturing residues. The ultrasonic cleaners (b) (4) (b) (4) have never been validated. No installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ) has been performed in accordance with Section 3.1 of procedure MAP-0011. Without validation of the current equipment, there is no assurance that your current cleaning process defined in procedure (MAP-0010, Rev G, dated			
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2/13/2025) consistently achieves effective cleaning of orthopedic implants. These cleaners have been used to process a quantity of (b) (4) orthopedic implant components from 11/11/2024 through 12/18/2025. 2. Your previous ultrasonic cleaning process (from approximately 2009 to 11/10/2024) had no assurance that the cleaning process can consistently produce conforming product. Previous validation attempts on decommissioned equipment used from approximately 2009 until 11/10/2024 are inadequate as they did not provide assurance that the ultrasonic cleaning process consistently produces product that is free from manufacturing residues: a. <i>Cleaning Implants Validation Plan</i>, VAP-19-01 (signed 9/23/2019) references former equipment SharperTek Stamina XP (ID MARS-182) and Digital Pro PS-40A (ID unknown). The validation plan included analytical testing protocols for gravimetric analysis, total organic carbon (TOC) testing, and cytotoxicity testing. However, your firm: i. Failed to produce a validation report to demonstrate this validation plan was executed. However, your firm provided third-party test results for analytical testing completed on 9/29/2022 on a quantity of (b) (4) UHMWPE knee implants produced via Job Number (b) (4) (b) (4) but there is no documentation of the ultrasonic cleaning process parameters used for this production lot. ii. Failed to include an IQ or PQ as part of the validation plan in accordance with Section 3.1 of procedure MAP-0011. iii. Failed to include a validation plan for cleaning effectiveness of different part geometries, loading configurations, and tank capacity utilization, including worst-case scenarios such as maximum loading density and complex part geometries. iv. Failed to include a valid statistical rationale for a sample size of (b) (4) pieces of UHMWPE			
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for gravimetric analysis and TOC analysis and (b) (4) piece for cytotoxicity testing. v. Failed to consider other implant device materials cleaned via the process, such as Radel, (b) (4) Ultem, and Acetal Copolymer. b. <i>Cleaning Implants Validation Plan</i>, VAP-17-01 (signed 9/8/2021) references former equipment (b) (4) (b) (4) Your firm: i. Failed to produce a validation report to demonstrate this validation plan was executed. ii. Failed to include analytical testing (such as gravimetric analysis, total organic carbon (TOC) testing, and cytotoxicity testing) as only visual inspection of (b) (4) UHMWPE samples under (b) (4) magnification was conducted with pass/fail limited to (b) (4) appearance, which does not demonstrate actual cleaning effectiveness or removal of manufacturing residues. iii. Failed to validate different loading configurations, part geometries, and tank capacity scenarios that could affect cleaning effectiveness. iv. Failed to include in the validation plan the drying step using (b) (4) air specified in your procedure MAP-0010. v. Failed to consider other implant materials cleaned via the process, such as Radel, (b) (4) Ultem, and Acetal Copolymer. vi. Failed to include cavitation verification as part of the validation plan. B. Your firm has not validated the (b) (4) air system used to dry orthopedic implant components			
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following ultrasonic cleaning. Specifically, the (b) (4) air (b) (4) finished devices but lacks: 1. Validation demonstrating the system does not introduce contamination to finished devices, including Installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ) in accordance with Section 3.1 of procedure <i>Validation Process</i> (MAP-0011). 2. Air quality specifications for moisture, oil, particles, and microorganisms. 3. Ongoing monitoring of air quality parameters at points of use where (b) (4) air contacts cleaned orthopedic implant components. C. Your firm has not validated the (b) (4) used for final inspection of orthopedic implants. No installation qualification (IQ), operational qualification (OQ), or performance qualification (PQ) has been performed in accordance with Section 3.1 of procedure <i>Validation Process</i> (MAP-0011) to demonstrate the system can reliably measure critical dimensions and detect conforming versus nonconforming orthopedic implants. For example, this equipment is used to inspect 17 of (b) (4) final dimensions for the (b) (4) (b) (4) using an (b) (4) (b) (4)			
OBSERVATION 2 Procedures have not been adequately established to control product that does not conform to specified requirements. Specifically, your firm's procedures <i>Control of Non-Conforming Product</i>, QAP-0008, Rev E, dated 9/15/2021 has not been implemented. For example:			
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- A. Your firm failed to document nonconformances in your electronic system (b) (4) in accordance with Section 2.1.1 of QAP-0008 which requires documenting nonconformities on the router and by a nonconformance report in (b) (4). More specifically,
1. No nonconformances identified prior to product release are documented in (b) (4); your firm only opens nonconformance records in (b) (4) for customer returns (i.e., complaints).
 2. Your firm instead documents nonconformances on a *Discrepant Material Log* (QAF-0016) as referenced in procedure *Visual Inspection* (QAP-0011). However, QAP-0011 is inadequate as it provides no instructions for evaluation, investigation, or disposition of nonconforming products documented on the log. Additionally, none of the 37 nonconformances listed from 7/11/2025 through 1/6/2026 were documented in (b) (4) as required by QAP-0008. For example, (b) (4) unit of the (b) (4) Job Number (b) (4) documented on the log as nonconforming for surface finish was not documented in (b) (4).
- B. Your firm's Quality Manager stated previous *Discrepant Material Logs* (QAF-0016) were discarded following (b) (4) reviews, with only the current log covering nonconformances from 7/11/2025 through 1/6/2026 available during the inspection. Thus, there is no record of individually logged nonconformances prior to 7/11/2025 although (b) (4) review charts document that nonconformances occurred during earlier periods.
- C. Your firm failed to conduct nonconformance investigations in accordance with Section 3 of QAP-0008. No evidence of investigations or evaluations to determine the need for investigations exist for any nonconformances documented in the *Discrepant Material Log*.
- D. Your firm failed to document disposition of nonconforming product in accordance with Section 3 of QAP-0008. More specifically:
1. The *Discrepant Material Log* shows blank fields for (b) (4) for all 37 nonconformances, indicating no documented disposition.
 2. Job Number (b) (4) (knee implant) in the *Discrepant Material Log* shows (b) (4) unit was

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scrapped for (b) (4), the log was revised to cross out this entry, and review of the DHR revealed this unit was subsequently deemed conforming and released for distribution. E. Your firm failed to handle rework in accordance with Section 3.2.1 of QAP-0008, which requires rework instructions, identification of the individual performing rework, date of completion, and re-inspection to original requirements. For Job Number (b) (4) (knee implant), your firm's Quality Engineer stated an inclusion came off after cleaning to address a nonconforming part, but the DHR contains no documentation of who performed this rework, when it was completed, or verification that the device met specifications after rework.							
OBSERVATION 3 Procedures for monitoring and control of process parameters for a validated process have not been adequately established. Specifically, A. Your firm has not established procedures for cavitation monitoring of the ultrasonic cleaning process. More specifically: 1. Your personnel described performing cavitation verification every (b) (4) months by (b) (4) (b) (4) (b) (4). However, no written procedures exist for this process monitoring activity, including: (1) steps for performing the cavitation test, (2) specifications for (b) (4) size and (b) (4) preparation, (3) acceptance criteria for determining adequate cavitation, and (4) documentation requirements for test results and pass/fail determinations. 2. While your firm maintains a "Work Center Maintenance Summary" showing cavitation tests							
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completed every (b) (4) months from March 2022 through October 2025, this documentation contains no test results, acceptance criteria, equipment identification (which tank was tested), or evidence that the tests were performed.

B. Your firm has not established adequate procedures for monitoring (b) (4) air quality used in the orthopedic implant cleaning process. More specifically:

1. Your firm's (b) (4) air monitoring procedure (MAP-0003) is inadequate for a validated cleaning process as it relies (b) (4) on visual assessment using a (b) (4) which cannot detect microbial contamination, quantify particulate levels, or measure moisture content to established specifications for medical device manufacturing. Specifically, no quantitative (b) (4) air quality specifications or acceptance criteria have been established to ensure the (b) (4) air system does not introduce contamination to cleaned orthopedic implant components.
2. Your firm only monitors (b) (4) air quality at the (b) (4) units themselves but has not established monitoring procedures for points of use on the manufacturing floor, such as where (b) (4) air (b) (4) orthopedic implant components during the drying process.
3. Your firm has not adequately implemented procedure *Air (b) (4) Cleanliness Check*, MAP-0003, Rev A, dated 1/15/2011. While your personnel verbally described performing (b) (4) air monitoring using a (b) (4) method similar to MAP-0003 to check for moisture, oil, particulate matter, and other contaminants, your firm:
 - a. Does not use the required form MAF-0003 as specified in procedure MAP-0003 to document monitoring activities.
 - b. Does not maintain the required "Air (b) (4) Cleanliness Check Log Book" as specified in MAP-0003.
 - c. Performs monitoring every (b) (4) months instead of the required (b) (4) frequency per MAP-

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0003. 4. Work Center Maintenance Summary records for (b) (4) and (b) (4) (b) (4) show "Check Air" entries from 2024-2026, but contain no test results, pass/fail determinations, or acceptance criteria. Therefore, there is no evidence that (b) (4) air quality meets specifications. 5. Recent (b) (4) maintenance records from December 2025 document (b) (4) is producing smoke" and "excessive amount of oil coming out of (b) (4)" but no evaluation was performed to determine the impact on (b) (4) air quality used for drying cleaned orthopedic implant components during the period of (b) (4) malfunction.			
OBSERVATION 4 Procedures for device history records have not been established. Specifically, A. Your firm has not established procedures for device history records (DHRs) to demonstrate that each device is manufactured in accordance with the device master record (DMR). B. DHRs do not demonstrate that devices were manufactured in accordance with the DMR. More specifically, there is no documentation that ultrasonic cleaning of orthopedic implants was conducted in accordance with <i>Procedure For Cleaning Plastic Trials and Implants</i> (MAP-0010). For example, 9 of 9 DHRs reviewed (Job Numbers (b) (4) (b) (4) (b) (4) for the (b) (4) (b) (4) fail to include any documentation of ultrasonic cleaning despite your firm's Quality Manager claiming (b) (4) parts undergo cleaning per MAP-0010. This device is a component of the (b) (4)			
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Since 11/11/2024, your firm distributed a quantity of (b) (4)			
OBSERVATION 5 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established. Specifically, your firm's procedure <i>Customer Complaint</i>, QAP-0019, Rev B, dated 12/22/2014 is inadequate in that it: (1) does not specify requirements for complaint investigations, and (2) does not ensure all complaints are handled in a uniform and timely manner. Additionally, your firm failed to conduct complaint investigations. Review of 6 complaint records for orthopedic implants revealed that all 6 (complaint numbers 10560, 10615, 10620, 10648, 10698, and 10699) lacked a documented investigation. Between 12/1/2023 to 12/16/2025, you firm received approximately 104 customer complaints related to devices that did not meet specifications.			
OBSERVATION 6 Document control procedures have not been adequately established. Specifically, your firm's procedure <i>Control of Quality Records</i>, QAP-0004, Rev A, dated 1/15/2015, has not been followed, as Section 2.1(e) requires quality records to be (b) (4) (b) (4) Your firm's Quality Manager stated that previous <i>Discrepant Material Logs</i> (QAF-0016), which document nonconformances, were discarded following (b) (4) reviews, resulting in only approximately 6 months of nonconformance records being retained (from 7/11/2025 through 1/6/2026).			
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OBSERVATION 7

Process control procedures that describe any process controls necessary to ensure conformance to specifications have not been established.

Specifically, your firm has not established procedures or work instructions for conducting final inspection of orthopedic implants using the (b) (4)

(b) (4) This equipment is used to inspect critical dimensions of finished devices, including 17 of (b) (4) final dimensions for the (b) (4) but no documented procedures exist to ensure consistent inspection methods, acceptance criteria, or operator requirements for this final quality control inspection process.

OBSERVATION 8

Individuals who conduct quality audits have direct responsibility for the matters being audited.

Specifically, internal quality audits are conducted by individuals who have direct responsibility for the quality system. Your firm's (b) (4) internal quality audits conducted in 2023, 2024, and 2025 were conducted by your firm's President and your firm's Quality Manager / Management Representative.

Additionally, procedure *Internal Auditing Specification*, QAP-0010, Rev E, dated 1/31/2022 is inadequate as it does not specify that quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited.

OBSERVATION 9

Sampling plans are not based on valid statistical rationale.

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Specifically, your firm's procedure *In-Process and Final Inspection Procedure*, QAP-0013, Rev C, dated 9/20/2013, requires that (b) (4)

(b) (4) " during in-process inspection but provides no valid statistical rationale for this sampling plan.

OBSERVATION 10

Procedures for training and identifying training needs have not been adequately established.

Specifically, your firm's procedure *Competency, Awareness, & Training* (QAP-0005, Rev C, dated 5/25/2012), Section 3.1.2.1, was not adequately implemented as there was no evidence that your firm's Quality Engineer received on-the-job training "for all required tasks and/or operations for which the employee will be performing or have responsibility."

OBSERVATION 11

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm's procedure *Corrective Action*, QAP-0009, Rev F, dated 9/15/2021 was not adequately implemented in that your firm was unable to provide objective evidence of corrective action implementation or verification of effectiveness in accordance with Sections 2.3.7 and 2.3.10 of QAP-0009. Examples include CAPA 10309 (knee implant) opened 4/10/2023 and CAPA 10310 (hip implant) opened 2/20/2023.

***DATES OF INSPECTION**

12/16/2025(Tue), 12/17/2025(Wed), 12/18/2025(Thu), 12/22/2025(Mon), 1/05/2026(Mon), 1/06/2026(Tue), 1/08/2026(Thu), 1/14/2026(Wed), 1/16/2026(Fri)

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Annotations to Observations Observation 1: Observation 2: Observation 3: Observation 4: Observation 5: Observation 6: Observation 7: Observation 8:			
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Observation 9:

Observation 10:

Observation 11:

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."