DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	3/16/2026-3/19/2026
	FEI NUMBER 3009446038

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Brian More, President

FIRM NAME	STREET ADDRESS
Nanovis LLC	5865 E State Road 14
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbia City, IN 46725-9237	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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures for validation of processes did not adequately include statistical techniques with rationale for sample sizes and use of specific methods, procedures, and acceptance criteria.

Specifically,

oMaster validation of the titanium anodize nano surface treatment for titanium implants and master validation adoption for the titanium anodize nano surface treatment of (b) (4) do not adequately establish acceptance criteria to show that the anodize nano surface treatment will meet specification requirements.

Per the (b) (4) Engineering Drawing (b) (4) (b) (4) 07 07/21/2022 note 10, nanotube anodize screw thread specifications are documented per SPE-00022. Per Spine Manufacturing Specification: Nanotube Anodization SPE-00022 Rev A 08/22/2025, page 2 section 7.2.1 through 7.3, parts are to be processed in general accordance with Nanovis work instruction NW 7.5.1.1-58 for titanium nanotube anodization and calcium phosphate deposition to yield the following physical properties: Calcium phosphate does not cover nanotube openings, (b) (4) tube diameter, if the entire part is not intended to be nanotube anodized, the feature(s) or zone(s) to be anodized with nanotubes should be defined on the engineering drawings.

However, the following acceptance criteria were not established to show that these specifications are met.

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	Suyang Qin, Investigator Shawn Choi, Investigator X Shawn Choi Investigator Signed By: 2004265134 Date Signed: 03-19-2026 14:58:43	3/19/2026

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☐Your organization did not document acceptance criteria for how much of the surface intended to be nanotube anodized will be covered by nanotubes as an output of the process.

Per (b) (4) – Master Validation Adoption (b) (4) 10/24/2025 pages 1-2, for the Highridge screws used in the process validation, you identified that between (b) (4) and (b) (4) of the (b) (4) surface that was intended to be nanotube anodized is covered by nanotubes. Your organization did not provide a rationale for why (b) (4) coverage of the intended area with nanotubes is sufficient for the product to meet its specification.

☐Your organization did not document acceptance criteria for what percentage of nanotubes will be within the range of (b) (4) tube diameter.

Per (b) (4) Master Validation Adoption (b) (4) 09/12/2025 page 4, the acceptance criteria for nanotube diameter / morphology is documented as (b) (4) (b) (4) nanotube structures between (b) (4) and (b) (4) measured using the (b) (4) However, per (b) (4) from (b) (4) Master Validation Adoption (b) (4) (b) (4) 10/24/2025, a number of nanotubes can be observed to be at or greater than 100nm. Per the organization's Principle Scientist the images were evaluated as passing results because the visual (b) (4) of all nanotubes present on the image appear within the specification range of (b) (4) Your organization did not document the acceptance criteria can be an (b) (4) value. Spine Manufacturing Specification: Nanotube Anodization SPE-00022 Rev A 08/22/2025 does not document the (b) (4) requirement as an (b) (4) value.

☐Process validations did not include a surface characterization to determine if the diameter of the nanotubes formed during the process are consistent and homogenous across the intended surface.

Per Surface Characterization of nanoVIS Ti Surface on (b) (4)

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(b) (4) Memo 08/29/2025, your organization documented that an analysis of (b) (4) nanotubes show that the nanotubes created during the anodization average at (b) (4) with an (b) (4) standard deviation of (b) (4) This surface characterization study shows that at greater than (b) (4), the nanotubes would fall out of the acceptance range of (b) (4) This surface characterization was not performed as part of a validation. Your organization does not have objective evidence that this surface characterization is repeatable at all ranges of acceptable process conditions. Your organization did not establish if this surface characterization establishes that the process is capable of producing a product with a consistent and homogenous surface.

oMaster validation of the titanium anodize nano surface treatment for titanium implants and master validation adoption for the titanium anodize nano surface treatment of (b) (4) do not adequately establish rationale for sample sizes. Per (b) (4) Master Validation Adoption (b) (4) 09/12/2025 page 4, nanotube diameter/morphology and calcium phosphate features are tested via (b) (4) for visual attributes with a sampling frequency of (b) (4). Per the protocol page 3 section 8.1.3.4.1, (b) (4) representative image shall be captured for (b) (4) determination. Your organization has not established in the validation that the diameters of the nanotubes are consistent and homogenous across the anodized surface. Your organization did not document a rationale for why a sample size of (b) (4) image in each of (b) (4) samples is statistically significant to determine that anodization across the trial will meet nano surface specifications.

Per (b) (4) pFMEA Rev A 11/12/2025, nanosurface nonconformities are documented with a severity (b) (4) out of (b) (4) Per (b) (4) Report RMR-10098 Rev B 01/24/2026, nanotube anodization nonconformities are documented with a severity (b) (4)

OBSERVATION 2

Production controls do not include implementation of monitoring and measurement of process parameters and product characteristics.

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Specifically,

oCritical process parameters of the titanium anodize nano surface treatment for titanium implants validated process are not adequately monitored. Per 2025 Nano Process Master Validation Plan OQ Protocol (b) (4) 08/22/2025 page 2 table 2.4A, critical process parameters include Acid Concentration and (b) (4) Concentration. These process parameters are not adequately monitored in the following ways:

- Per Titanium Anodize Nanosurfacing Setup Sheet 206HXXX-00 (b) (4) (b) (4) 11/20/2025 the monitoring for the Acid Concentration is reference only, performed only at the beginning of the day, and is a measurement by titration volume instead of concentration. Your organization produces multiple lots per production day, your monitoring does not provide assurance that the acid concentration is adequately maintained within the validated process range of (b) (4) for each batch manufactured.

  Additionally, your organization has not adequately established that the titration reference range documented as (b) (4) can be used to accurately monitor the acid concentration tolerance range of (b) (4)

- Per Titanium Anodize Nanosurfacing Setup Sheet 206HXXX-00 (b) (4) (b) (4) 11/20/2025 the monitoring for the (b) (4) Concentration is reference only, performed only at the beginning of the day, and is a measurement by (b) (4) instead of concentration. The process monitoring procedure does not document process limits for (b) (4) value where it would indicate the process is operating outside of the validated range. Your organization produces multiple lots per production day, your monitoring does not provide assurance that the (b) (4) is adequately maintained within the validated process range for each batch manufactured.

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Additionally, your organization has not adequately established how (b) (4) relates to (b) (4) concentration in a way that can be used to accurately monitor the process parameter.

oProduct characteristics of the nanotubes formed in the anodization process are not adequately monitored. Per (b) (4) : Nanotube Anodization SPE-00022 Rev A 08/22/2025, page 2 section 7.2.1 the nanotube specifications are Calcium phosphate does not cover nanotube openings, (b) (4) tube diameter.

Per Titanium Anodize Nanosurfacing Operation NW 7.5.1.1-58 Rev T 11/04/2025 page 4 section 5.3 the product characteristic monitoring include sample (b) (4) during the first production run and last production run of the day. Per Titanium Anodize Nanosurfacing Setup Sheet 206HXXX-00 (b) (4) 11/20/2025, (b) (4) are (b) (4) production parts and representative samples. Per production records sampled, (b) (4) is ran with the first and the last production run of the day. Per Attachment 6.2 Imaging Zones for Nano FortiFix Screws NW 7.5.1.1-59 Rev A 11/05/2024, page 1 section 1.1, at least (b) (4) on the sampling (b) (4) or implant surface will be selected for magnification. Per Titanium Anodize Nanosurfacing Inspection NW 7.5.1.1-59 Rev F 11/05/2024 page 3 section 5.4.3, (b) (4) inspection method, each (b) (4) is inspected under (b) (4) magnification for uniformly round nanotube structures between (b) (4) and (b) (4) and to assess if calcium phosphate is covering the nanotubes. Per the procedure page 3 section 5.4.2, 1 inspection image from each sample (b) (4) is captured and saved.

Your organization produces multiple lots per production day. You have not documented why your product characteristic monitoring of (b) (4) out of (b) (4) , in (b) (4) a production day is sufficient to demonstrate that all batches manufactured during that day conforms to product specifications.

Per (b) (4) pFMEA Rev A 11/12/2025, nanosurface nonconformities associated with incorrect processing times/parameters and inadequate process monitoring documented

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with a severity (b) (4) . Per (b) (4) 01/24/2026, nanotube anodization nonconformities are documented with a severity (b) (4) .

OBSERVATION 3

Requirements for the work environment, and the procedures to monitor and control the work environment, were not adequately documented where conditions for the work environment can have an adverse effect on product quality.

Specifically, the titanium anodize nano surface treatment work environment does not have adequate requirements and is not adequately monitored and controlled.

Per Spine Manufacturing Specification: Nanotube Anodization SPE-00022 Rev A 08/22/2025 page 2 section 6.1, all manufacturing and finishing processes, including final manufacturing cleaning, should occur (b) (4) nanotube anodization. Per the specification page 2 section 6.3.1, (b) (4) and/or (b) (4) cleaning systems are prohibited following nanotube anodization and deposition; (b) (4) is recommended prior to final packaging. Per excerpt from (b) (4) (b) (4) 09/26/2025, the product is sterilized via (b) (4) .

Per Facilities Resources NP 6.3 Rev E 01/09/2026 page 3 section 5.2.6.d, the nanosurfacing room work environment monitoring shall be controlled per Process Monitoring and Equipment Monitoring NW 7.5.1.1-66. However, there is no documentation of environmental monitoring requirements in Process Monitoring and Equipment Monitoring NW 7.5.1.1-66 Rev A 08/22/2025. Your organization has not documented environmental controls or monitoring requirements for an environment where product intended to be (b) (4) sterilized and has been subjected to final manufacturing cleaning is processed. Product contamination within this work environment may compromise the product's sterility assurance.

Per (b) (4) pFMEA Rev A 11/12/2025, nanosurface nonconformities associated with product contamination and improper environmental exposure are documented with a severity (b) (4) . Per (b) (4) 01/24/2026, product

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contamination with biological agents during nanotube anodization are documented with a severity (b) (4) (b) (4)

OBSERVATION 4

Purchasing information does not adequately describe or reference the product to be purchased, including requirements for product acceptance, procedures, processes, and equipment.

Specifically,

oYour organization did not adequately document purchasing requirements for (b) (4) used in the titanium anodize nano surface treatment process.

Per 2025 Nano Process Master Validation Plan (b) (4) 08/22/2025 page 4, the (b) (4) used in the titanium anodize nano surface treatment is (b) (4). Per the protocol, (b) (4) is used for rinse tanks. Per Titanium Anodize Nanosurface Set-up NW 7.5.1.1-67 Rev C 11/04/2025 page 5, (b) (4) is accessed from the (b) (4) in the (b) (4) room. Per the procedure page 5 section 5.2.8, (b) (4) is used to fill all rinse tanks. Per Titanium Anodize Nanosurfacing Operation NW 7.5.1.1-58 Rev T 11/04/2025 page 9, section 5.4.10.c, in addition to the (b) (4) rinse, an additional sink rinse may be performed for porous product.

The (b) (4) used during all steps of the titanium anodize nano surface treatment is from an external supplier and not controlled by the organization. Your organization has not documented purchasing requirements for the (b) (4) as a product, or the (b) (4) generation as a process.

Additionally, per Microbial Enumeration of Water Test Report 100148 02/16/2026, microbial enumeration of water from samples taken from implant sink, hose line, labware sink, deposition tank and deposition rinse tank resulted in between 22 CFU (colony forming units) and 451 CFU for HPC (heterotrophic plate count) and between 33 CFU and 528 CFU for yeast and mold.

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Your organization does not have a documented upper limit for the acceptable number of CFU in microbial enumeration in the (b) (4) supply. Per Spine Manufacturing Specification: Nanotube Anodization SPE-00022 Rev A 08/22/2025 page 2 section 6.1, all manufacturing and finishing processes, including final manufacturing cleaning, should occur prior to nanotube anodization. Per excerpt from (b) (4) 09/26/2025, the product is sterilized via (b) (4) Your organization has not documented whether exposure of final cleaned product to this water supply will result in nonconforming product or negatively impact the product's sterility assurance.

Per (b) (4) pFMEA Rev A 11/12/2025, nanosurface nonconformities associated with product contamination are documented with a severity (b) (4) . Per (b) (4) (b) (4) 01/24/2026, product contamination with biological agents during nanotube anodization are documented with a severity (b) (4)

oYour organization did not adequately document purchasing requirements for the (b) (4) (b) (4) as an input into your organization's validated titanium anodize nano surface treatment process.

Per (b) (4) – Master Validation Adoption (b) (4) 10/24/2025 pages 1-2, for the (b) (4) used in the process validation, you identified that between (b) (4) and (b) (4) of the (b) (4) surface that was intended to be nanotube anodized is covered by nanotubes. Per your organization's Principle Scientist, the coverage of the surface of the (b) (4) by the nanotubes is limited by the amount of exposed titanium. Per your organization's Principle Scientist, the (b) (4) titanium surface may be covered by nanoscale debris left over from (b) (4) manufacturing processes.

Your organization did not document a purchasing requirement for the amount of exposed titanium surface on the (b) (4) necessary for the titanium anodize nano surface

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treatment to result in a nano coated surface that meets Spine Manufacturing Specification: Nanotube Anodization SPE-00022 Rev A 08/22/2025.

Per (b) (4) pFMEA Rev A 11/12/2025, nanosurface nonconformities are documented with a severity (b) (4). Per (b) (4) (b) (4) 01/24/2026, nanotube anodization nonconformities are documented with a severity (b) (4)

OBSERVATION 5

Changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the quality management system and medical device safety and performance were not adequately identified and implemented.

Specifically,

oCorrective actions implemented are not effective in documenting actions needed to ensure that nonconformities do not recur. For example,

- CAPA 130 documented a nonconformance where procedures were not updated to reflect the change in responsibilities when the organization took over nanosurfacing processes; the changes in responsibilities include the additional responsibilities related to work space, process equipment, preventive maintenance and calibration.

  Per the CAPA actions, corrections were implemented to revise Facilities Resources NP 6.3 and verify procedures, work instructions, and forms are in place for the responsibilities listed within the newly revised procedure. This CAPA was closed as effective on 05/08/2025.

  However, per Facilities Resources NP 6.3 Rev E 01/09/2026 page 3 section 5.2.6.d, the nanosurfacing room work environment monitoring shall be controlled per Process

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Monitoring and Equipment Monitoring NW 7.5.1.1-66. However, there is no documentation of environmental monitoring requirements in Process Monitoring and Equipment Monitoring NW 7.5.1.1-66 Rev A 08/22/2025. This CAPA did not result in establishing procedures to address all new responsibilities.

□CAPA 141 documented a nonconformance where the pFMEA for a product omitted process control documents established in the product's control plan such as NW 7.5.1.1-65 Titanium Anodize Nanosurfacing Parameters and NF 7.5.1-08 Titanium Anodize Nanosurfacing SetupSheet.

Per the CAPA actions, corrections were implemented to update pFMEAs from the scope to align with the control plan and update control of documents procedures and document approval procedures to prevent recurrence. The actions were completed on 11/07/2025 and the CAPA was closed as effective on 12/23/2025.

However, the same nonconformance was identified in (b) (4) pFMEA Rev A 11/12/2025 as this pFMEA did not include documents established in the (b) (4) Control Plan Rev 07 11/03/2025 such as Spine Manufacturing Specification: Nanotube Anodization SPE-00022 and NW 7.5.1.1-65 Titanium Anodize Nanosurfacing Parameters. This CAPA did not result in preventing recurrence of the nonconformance.

oCorrective actions are not implemented in accordance with established procedures; a rationale for not opening a corrective action was not documented in accordance with established procedures. For example,

□Corrective actions were not initiated to address nonconformances identified during internal audits.

Per Internal Audits NP 8.2.2 Rev E 08/08/2025 page 4 section 5.1.1, identified audit nonconformances shall be processed through Corrective and Preventive Actions and entered as a CAPA workflow in (b) (4) Per Quality Systems – Internal Audit (b) (4) 10/06/2025, 2 nonconformances were documented.

However, these nonconformances were not entered as a CAPA; your organization has not documented any corrective actions associated with these nonconformances.

☐ Corrective actions were not initiated to address negative trends in supplier monitoring and no rationale for the lack of action was documented.

Per Supplier Management NP 7.4.1 Rev L 01/09/2026 page 6 section 5.4.2, supplier ratings and approvals are based on performance data from the previous (b) (4) data is analyzed during management review to identify trends that may necessitate remedial action. Management shall determine and document any such actions or justify why no action is required.

Per 2025 (b) (4) Management Review data for critical supplier status monitoring, a critical supplier was identified to be conditionally approved with decreasing status scores for (b) (4) However, no remedial action or rationale for no action was documented.

OBSERVATION 6

Changes to quality management system processes were not adequately controlled in accordance with requirements and evaluated for their impact on the quality management system and the medical devices produced.

Specifically, when moving your validated manufacturing equipment and changing the operation location

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for a validated manufacturing process, your organization did not adequately evaluate the impact of that change on medical devices in accordance with established procedure.

Per Design and Development NP 7.3 Rev M 02/20/2025 page 12 section 6.7.4.1, initial releases and changes to design and development and engineering documents require formal documentation on the (b) (4) and subsequent approval/release. Per the procedure page 13 section 6.7.4.5, during the review, the lead (b) (4) evaluates if the change has any effect on product in process, already delivered, and/or constituent parts.

Per Supplier Change Notification SQ-10416 01/07/2026, page 1, validated equipment used to qualify the anodize process is moved within the building and requalified. Per the change notification page 2, the nano processing room moved and is expanded. This change was sent to the organization's customer for approval.

However, your organization has not documented an (b) (4) with an independent evaluation of the impact of the change on medical devices manufactured using the moved equipment in the new environment in accordance with procedural requirements.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

Observation 5: Promised to correct

Observation 6: Promised to correct

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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."