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Public 510(k) Clarity Audit - K241992

Catalyft™ LS Expandable Interbody System (Lumbar Fusion)

Applicant: Medtronic Sofamor Danek USA,
Inc. FDA Decision Date: October 28, 2024
Audit Date: June 4, 2026
Audit #3 of the Public Clarity Audit series

Source document: FDA 510(k) database, K241992. Available at
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241992

Independent review notice. This audit relies exclusively on the public 510(k) Summary documents released by the FDA for K241992. Martinez Clarity has no affiliation with Medtronic. This audit is published for educational and methodology demonstration purposes only. The audited submission was successfully cleared by the FDA in October 2024. The findings below represent observations of documentary clarity. They are not regulatory deficiencies, and they do not call into question the cleared status of the device.

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Executive Summary

This audit applies the Martinez Clarity 4-Axis methodology to the public 510(k) Summary of the Catalyft™ LS Expandable Interbody System (K241992) from Medtronic Sofamor Danek.

8 findings were identified:

- 4 Red: Likely to trigger a Refuse to Accept (RTA) hold or an Additional Information (AI) request letter under current 2026 review conditions.
- 4 Yellow: Likely to slow review under current reviewer bandwidth constraints.
- 0 Green: Cosmetic, no impact on review.

This submission was cleared by the FDA in October 2024. Under the review conditions of that period, none of these gaps were blocking. Today, however, with the tightening of acceptance criteria, the workforce reduction at CDRH, and the more rigorous application of standards traceability requirements, similar documentary gaps systematically trigger AI request letters on submissions currently under review. The typical added delay is 45 to 60 days.

The most notable pattern in this submission is the combination of two distinct credibility risks. First, a semantic mismatch on the "Common Name" of the device: a Class II intervertebral body fusion device labeled with the common name "**Integrated Bone Screws**", which describes a component rather than the device itself. Second, a Performance Data section that lists test standards as bullet points but **reports no quantitative outcomes**, no comparison metricscc, and no narrative tying the tests to the substantial equivalence argument. For a major manufacturer of this profile, the structural opacity of the Performance section is unusual.

Axis	Findings	Highest severity
1. Terminology Consistency	2	Red
2. Requirements to Tests Traceability	2	Red

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Axis	Findings	Highest severity
3. RTA Acceptance Checklist Alignment	2	Yellow
4. Device-Specific Compliance	2	Red

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Methodology

This audit follows the Martinez Clarity 4-Axis methodology.

Axis 1. Terminology Consistency. Verification of device names, predicate names, components, and technical terms across all sections. Drift signals either a rushed submission or a multi-author draft without a final harmonization pass.

Axis 2. Requirements to Tests Traceability. Verification that every performance claim and risk statement is anchored to a named test protocol, a recognized standard, and a quantified result. Unanchored claims invite reviewer clarification requests.

Axis 3. RTA Acceptance Checklist Alignment. Verification of the public-visible elements of the FDA Refuse to Accept Policy for 510(k)s: complete predicate identification, alignment of indications for use, and the rigor of the substantial equivalence conclusion.

Axis 4. Device-Specific Compliance (Implants and Class II Mechanical, 2026 context): validation of biocompatibility traceability (**ISO 10993**), mechanical testing standards versions (ASTM F-series), risk management (**ISO 14971**), nanotechnology guidance reference accuracy, and the precision of indicainotions for use statements relevant to surgeon decision-making.

Severity scale:

- Red: High likelihood of RTA hold or immediate AI request under current FDA review conditions.
- Yellow: Likely to slow review, generate secondary clarification questions.
- Green: Cosmetic gap, no impact on the decision.

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Findings

AXIS 1, TERMINOLOGY CONSISTENCY

Finding 1 - "Common Name" labeled as a component, not the device [Red]

Axis 1 : Terminology Consistency Page reference: 510(k) Summary, page 1 (administrative header table)

Cited text :

Name of Device: Catalyft™ LS Expandable Interbody System Common Name: Integrated Bone Screws Classification Name : Intervertebral Body Lumbar Fusion Device with Bone Graft (21 CFR 888.3080)

Risk analysis. The device is a Class II expandable interbody fusion device per 21 CFR 888.3080, Product Code OVD. The integrated screws are a component used to anchor the implant when configured as a stand-alone device. Labeling the "Common Name" as "Integrated Bone Screws" describes a component, not the device category. The analogy: labeling a vehicle's Common Name as Integrated Wheels.

Under current 2026 review climate, the Common Name field is used by FDA automated tools and by manual reviewers as a sanity check against the Classification Name and the Product Code. A semantic mismatch at this level is a recognizable RTA trigger. The discrepancy is also visible to downstream users of the FDA 510(k) database, where searches by common name will fail to surface this device under its actual category.

Recommended fix. Replace the Common Name with a term consistent with the Classification Name and Product Code, for example, "Expandable Lumbar Interbody Fusion Device" or "Intervertebral Body Fusion Device with Integrated Screws".

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Finding 2 - Inconsistent trademark notation on the nanoLOCK surface technology [Yellow]

Axis 1: Terminology Consistency Page reference: 510(k) Summary, page 2 (Description section)

Cited text :

"nanoLOCK™ surface treatments designed to improve bone fixation" "nanoLOCK™ surface technology provides a microscopic, roughened surface" "nanoLOCK surface technology is specifically engineered to have nano textured features" "nanoLOCK surface technology demonstrates elements to be considered nanotechnology"

Risk analysis. Within a single paragraph, "nanoLOCK" appears both with and without the trademark notation (™). The product is registered as a Medtronic trademark, and the inconsistent use signals a copy-paste assembly from multiple source documents without a final harmonization pass. This is the canonical Axis 1 drift pattern.

By itself, the trademark notation is a minor cosmetic issue. In context, it is one of three terminology drift signals in this submission, and reviewers in 2026 use cumulative drift as a heuristic for assessing the overall documentary quality of a submission.

Recommended fix. Apply a consistent trademark notation across all occurrences of "nanoLOCK". The first mention per section should include the trademark, subsequent mentions follow a consistent style guide.

AXIS 2, REQUIREMENTS TO TESTS TRACEABILITY

Finding 3 - Performance Data section reports no quantitative outcomes [Red]

Axis 2: Requirements to Tests Traceability Page reference: 510(k) Summary, page 3 (Performance Data section)

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Cited text :

"The subject Catalyft™ LS implants with new subject integrated screws underwent the following mechanical tests to ensure that the main technological differences between the subject and predicate devices do not present a new worst-case : • Static and Dynamic Compression per ASTM F2077-22 • Static and Dynamic Compression Shear per ASTM F2077-22 • Subsidence per ASTM F2267-22 • Expulsion per **ASTM F-04.25.02.02** • Wear Debris per ASTM F1877 (2016) • Bone screw push out • MRI Safety Evaluation per ASTM F2503-23, ASTM F2182-19e2, ASTM F2052-21, F2213-17, F2119-07"

Risk analysis. The Performance Data section reports a list of tests performed without any quantitative result, comparison value, acceptance criterion, or narrative tying the outcomes to the substantial equivalence argument. The reader receives a list of standards and a closing claim ("do not present a new worst-case") without any data to substantiate it.

Medtronic is within its rights to redact specific R&D values in the public Summary, but the substantial equivalence argument relies on demonstrating performance equivalence to predicates. The Summary should at minimum state :

- that the test outcomes met the acceptance criteria specified in each standard,
- that the subject device performance was comparable to or better than the predicate device in each test category, and
- a brief narrative tying these outcomes to the substantial equivalence conclusion.

Under the current 2026 review climate, a Performance Data section structured as a bullet list of standards with no narrative outcome is a documented AI request trigger. The reviewer will request the explicit acceptance criteria statement, the test outcome summary, and the comparison to the predicate.

Recommended fix. Restructure the Performance Data section as a table : Test | Standard | Acceptance Criteria | Outcome | Comparison to Predicate. Even high-level qualitative outcomes ("Met acceptance criteria. Performance comparable to Predicate 1.") protect the substantial equivalence argument while keeping proprietary numerical data confidential.

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Finding 4 - ASTM F-04.25.02.02 cited as a published standard [Red]

Axis 2: Requirements to Tests Traceability Page reference: 510(k) Summary, page 3 (Performance Data, Expulsion test)

Cited text :

"Expulsion per ASTM F-04.25.02.02"

Risk analysis. The notation "ASTM F-04.25.02.02" does not follow the format of a published ASTM standard. Published ASTM standards use the format "ASTM Fxxxx-yy" (for example, ASTM F2077-22, also cited in the same list). The notation "F-04.25.02.02" corresponds to the ASTM committee and task group numbering system, specifically the F04 committee on Medical and Surgical Materials, subcommittee F04.25 on Orthopaedic Materials and Implants. References at this level of the committee hierarchy designate work items or task group activities, not published consensus standards.

Citing a test as performed "per ASTM F-04.25.02.02" while listing it alongside genuine published standards (ASTM F2077-22, ASTM F2267-22, ASTM F1877:2016, ASTM F2503-23, ASTM F2182-19e2, ASTM F2052-21, F2213-17, F2119-07) creates the impression of a consensus standard where there is either a work item, an internal test method, or an unfinalized standard draft. Under the current 2026 review climate, a reviewer or an automated FDA standards-recognition check will flag the reference as unrecognized and request clarification on the exact methodology used for the expulsion test.

Recommended fix. Clarify whether the expulsion test was performed under

- a draft ASTM work item, in which case cite the work item identifier (typically WKxxxxx) and note its draft status,
- an internal Medtronic test protocol, in which case name the protocol with its version number, or
- a published standard that may have been misformatted. The current notation cannot be independently verified by a reviewer.

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AXIS 3, RTA ACCEPTANCE CHECKLIST ALIGNMENT

Finding 5 - Indications for Use contain nested conditional carve-outs to the stand-alone claim [Yellow]

Axis 3: RTA Acceptance Checklist Alignment Page reference: Indications for Use (FDA form, K241992 IFU page) and 510(k) Summary page 3

Cited text :

"The Catalyft™ LS Expandable Interbody System device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the Catalyft™ LS Expandable Interbody System device is intended to be used with 4 titanium alloy screws. If the physician chooses to use less than 4 or none of the provided screws, additional supplemental fixation in the lumbar spine must be used to augment stability. Implants with lordosis angles greater than 20° are intended to be used with 4 screws and supplemental fixation."

Risk analysis. The IFU asserts a stand-alone indication, then qualifies it with three nested conditions:

1. Stand-alone requires the 4 integrated screws.
2. If fewer than 4 screws are used, supplemental fixation is mandatory (no longer stand-alone).
3. If the implant lordosis angle exceeds 20°, supplemental fixation is mandatory even with 4 screws (no longer stand-alone).

The cumulative effect of these carve-outs is that the "stand-alone" claim applies only to a specific subset of the device configurations (those with lordosis ≤20° and the full 4-screw configuration). The IFU does not state this restriction up front. A surgeon reading the IFU must reconstruct the actual stand-alone subset by parsing the cascade of conditions.

Under current 2026 review climate, IFU statements that require the reader to mentally reconstruct the indication from layered conditions are a documented source of AI requests.

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The reviewer will typically request a restructured IFU where the stand-alone indication is stated cleanly with its qualifying conditions presented as a single explicit boundary.

Recommended fix. Restructure the IFU paragraph to state the stand-alone indication with its boundary upfront, for example: "The device may be used as a stand-alone configuration in implants with lordosis ≤20° when configured with all 4 integrated titanium alloy screws. In all other configurations (fewer than 4 screws, or lordosis angles >20°), supplemental fixation must be used."

Finding 6 - Five predicates declared without characteristic-to-predicate mapping [Yellow]

Axis 3: RTA Acceptance Checklist Alignment Page reference: 510(k) Summary, page 1 (Predicate Devices table) and page 4 (Conclusion)

Cited text :

Predicate 1 (Primary Predicate) : Catalyft™ LS Expandable Interbody System (K212653) Predicate 2 : SOVEREIGN™ Spinal System (K091813) Predicate 3 : Crescent™ PEEK (K094025) Predicate 4 : Clydesdale™ Spinal System (K132897) Predicate 5 : Elevate™ Spinal System (K142559)

Risk analysis. Multi-predicate 510(k) submissions are allowed and common. However, when five predicates are declared, the FDA expects the submission to map which device characteristic or technological feature derives substantial equivalence from which predicate. The Catalyft 510(k) Summary declares the five predicates in the administrative section, reasserts them in the Conclusion, but provides no mapping between the predicates and the technological characteristics of the subject device.

The Comparison of Technological Characteristics section makes only a generic statement: "The subject device has the same fundamental scientific technology, indications for use, lengths, material, and torx drive as the predicate devices." It does not specify which predicate covers which characteristic. The reader cannot determine, for example, whether

the nanoLOCK surface treatment is supported by the primary predicate (K212653) or by another predicate in the list.

Under the current 2026 review climate, multi-predicate submissions without clear characteristic mapping generate AI requests asking the applicant to clarify the substantial equivalence chain.

Recommended fix. Add a Predicate Mapping table : one row per technological characteristic of the subject device, one column per predicate, with cell entries indicating which predicate establishes substantial equivalence for that characteristic.

AXIS 4, DEVICE-SPECIFIC COMPLIANCE (2026 CONTEXT)

Finding 7 - ISO 14971 and risk management process not mentioned [Red]

Axis 4: Device-Specific Compliance Page reference: 510(k) Summary, entire document

Cited text. No mention of ISO 14971 or risk management appears anywhere in the public 510(k) Summary.

Risk analysis. For a Class II implantable device incorporating nanotechnology surface features and integrated mechanical fixation components, ISO 14971:2019 compliance is expected. The Performance Data section claims that the mechanical tests confirm "the main technological differences between the subject and predicate devices do not present a new worst-case", but no risk management framework is referenced to substantiate the term "worst-case". The reader cannot determine which risks were identified, which mitigations were applied, or how verification testing was tied to identified risks.

Under the current 2026 review climate, the complete absence of any risk management framework reference in the Summary of a Class II implant with novel surface technology is among the most likely AI request triggers. The reviewer will request the risk management file references and the explicit ISO 14971:2019 compliance statement.

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Recommended fix. Add a dedicated Risk Management section referencing ISO 14971:2019, with cross-references between identified risks and the verification tests in the Performance Data section. State the risk management file revision number and date.

Finding 8 - FDA nanotechnology guidance and biocompatibility standards cited without precision [Yellow]

Axis 4: Device-Specific Compliance Page reference: 510(k) Summary, page 2 (Description section) and entire document for biocompatibility

Cited text :

"nanoLOCK surface technology demonstrates elements to be considered nanotechnology as outlined in the FDA nanotechnology guidance document." No mention of ISO 10993 or biocompatibility documentation appears in the Summary.

Risk analysis. Two related Axis 4 clarity gaps are bundled in this finding.

First, the nanotechnology reference. The Summary cites "the FDA nanotechnology guidance document" without naming the specific guidance or stating its publication date. The relevant FDA guidance is "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" (June 2014). Vague references to "the guidance document" are a documented AI request trigger because the reviewer must verify which version of which guidance was applied.

Second, biocompatibility. For a Class II implant in direct bone contact with novel nanotechnology surface treatment, biocompatibility documentation per ISO 10993-1 is expected. The 510(k) Summary contains no mention of ISO 10993, no biocompatibility statement, and no reference to biological evaluation testing. While the public Summary need not duplicate the full biocompatibility file, the omission of any biocompatibility reference for a bone-contacting nanotechnology surface is a structural gap.

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Recommended fix. Cite the FDA nanotechnology guidance by its full title and publication date. Add a Biocompatibility section referencing ISO 10993-1 and the relevant collateral standards (typically ISO 10993-5 and ISO 10993-10 for implants), with publication years.

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Conclusion

The audited submission (K241992, Catalyft™ LS Expandable Interbody System) was cleared by the FDA on October 28, 2024.

The documentary analysis identified 8 clarity gaps distributed across the 4 axes:

4 Red findings.

- "Common Name" labeled as a component (Integrated Bone Screws) rather than the device category (Intervertebral Body Fusion Device).
- Performance Data section reports no quantitative outcomes, no acceptance criteria, no comparison to predicates.
- ASTM F-04.25.02.02 cited as a standard while corresponding to a committee or work item identifier, not a published standard.
- ISO 14971 risk management process not mentioned anywhere in the public Summary.

4 Yellow findings.

- Inconsistent trademark notation on nanoLOCK surface technology within a single paragraph.
- Indications for Use contain nested conditional carve-outs that complicate the stand-alone claim.
- Five predicates declared without mapping to the technological characteristics of the subject device.
- FDA nanotechnology guidance cited without title or date, and ISO 10993 biocompatibility references absent.

These gaps did not block clearance under 2024 review conditions. Under the current 2026 review climate, the stricter application of standard traceability requirements, the workforce reduction at CDRH, and the more rigorous interpretation of Performance Data requirements

transform several of these gaps into systematic AI request triggers. The typical delay generated is 45 to 60 days per AI letter.

This audit demonstrates that documentary clarity gaps are not limited to small or first-time submitters. They appear in the public submissions of major manufacturers as well. For an implant with novel surface technology, the combination of an unmappable predicate cascade, an unanchored Performance section, and an absent risk management framework would today represent the most likely AI request triggers if the same dossier were filed under current review conditions.

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