April 10, 2025

Numalogics Inc
Marc-André Côté
Senior Director, Regulatory Affairs
4200 Boulevard Saint-Laurent
Suite #1100
Montreal, QC H2W 2R2
Canada

Re: U240247/S001
MDDT Name: ENDPOINT - numaScrew Virtual Pullout Test
MDDT Type: Non-Clinical Assessment
Dated: December 16, 2024
Received: December 16, 2024

Dear Marc-André Côté:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Medical Device Development Tool (MDDT) Qualification Package for the ENDPOINT - numaScrew Virtual Pullout Test.

We are pleased to inform you that the MDDT is qualified for the following Context of Use (COU):

This computational model is used to assess the axial pullout load of metallic medical bone screws in rigid polyurethane foam of grade 20 PCF in accordance with the ASTM F543-Annex 3 standard and can be used as a surrogate to physical testing.

To be tested using the computational model, a screw must meet the following specifications:

- Must be made from metallic material suitable for surgical implant applications with a Young's modulus greater than 50 GPa.
- Pitch must be between 1.0 - 3.0 mm, core diameter between 1.8 - 4.7 mm, major diameter between 2.7 mm and 7.7 mm, and thread depth between 0.4 and 2.5 mm.
- The insertion technique for the medical screw as described in its surgical technique guide must result in close to ideal engagement between the foam material and the screw, as the modeling approach employed in this tool creates perfect thread engagement with the foam material.

Additional considerations regarding the use of Endpoint - numaScrew Virtual Pullout Test:

- This computational model can, for instance, be used to perform comparisons to a comparator device (a device with a successful clinical history as justified by the user), for equivalence testing following screw design changes, or for identification of the worst-case scenario among different configurations of a screw system.

- If a comparator device is used, the pullout load of this comparator device should also be determined using the computational model to ensure equivalent testing conditions.
- The geometric details of the comparator device may be obtained from drawings, solid models, or any other source consistent with defining the model geometry. Engineering judgment shall be exercised to establish limits of manufacturing tolerances and the extent of model simplification. Any such judgements and simplifications and associated rationales shall be clearly documented in the test report.
- The computational model is intended to predict the pullout load of screws with complete thread purchase in the foam material. When assessing tapered screws, which have variations in thread or core diameter along their length, special attention should be given to ensure that the modeled scenario accurately reflects the real-world conditions being tested.
- Use of this model to evaluate screws with certain geometries and technological characteristics (e.g., unique thread designs, coatings, porosity, fenestrations, modularity, and geometries allowing flexibility) may result in inaccurate predications of pullout force; therefore, use of the tool in these scenarios might not be applicable or appropriate.

This qualification determination does not constitute marketing clearance or approval of this product as a medical device, and does not affect a previous clearance or approval of a device.

Once an MDDT is qualified for a specific COU, CDRH intends to accept its use by any medical device sponsor for that COU. When used within the above COU, the results of an assessment that uses this MDDT can be relied upon in medical device evaluation in a regulatory submission without the need to reconfirm with CDRH the suitability and utility of the MDDT. CDRH maintains the responsibility for evaluating regulatory submissions using information obtained from a qualified MDDT.

MDDT qualification does not obviate the need for a medical device sponsor to meet existing regulatory requirements, nor does it alter the benefit-risk threshold for regulatory decision-making related to a medical device; rather, it can facilitate the development and regulatory evaluation of a medical device by providing a more efficient and predictable means for collecting the necessary information to make regulatory assessments.

The use of an MDDT in a medical device clinical study does not change the IDE requirements for a given investigation.

CDRH will notify the public of its decision to qualify your MDDT. You have provided consent for FDA to make public certain information regarding this qualified MDDT. The Summary of Evidence and Basis of Qualification (SEBQ) will also be made public on the FDA's MDDT website (https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt).

Nothing about the MDDT program is intended to place limitations or requirements on MDDT licensing or fees, or the degree of access to intellectual property associated with an MDDT that a tool developer may give to a device sponsor.

You may request that CDRH incrementally expand or otherwise modify the qualified COU in response to new data or changing science by submitting a new qualification package. CDRH also intends to reconsider

qualification decisions as appropriate. For example, if the bases upon which an MDDT was qualified have changed, CDRH may re-evaluate the qualification decision.

If you have any questions regarding this letter that you would like to discuss further, please contact the MDDT Program at MDDT@fda.hhs.gov and reference your submission number provided above.

Sincerely,

EDWARD MARGERRISON -S

Digitally signed by EDWARD MARGERRISON -S
Date: 2025.04.10 14:47:49 -04'00'

Edward Margerrison, Ph.D.
Director
Office of Science and Engineering Laboratories
Center for Devices and Radiological Health

Enclosure:
Finalized Summary of Evidence and Basis of Qualification (SEBQ)

MDDT SUMMARY OF EVIDENCE AND BASIS OF QUALIFICATION FOR

Endpoint – numaScrew Virtual Pullout Test

numalogics

Background

MDDT Name: Endpoint – numaScrew Virtual Pullout Test
Submission Number: U240247
Date of Submission: 4 November 2024
Contact: David Benoit
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Tool Description and Principle of Operation

The 'Endpoint - numaScrew Virtual Pullout Test' Medical Device Development Tool (MDDT) is a computational model that predicts the axial pullout load of metallic bone screws in 20 PCF rigid polyurethane foam. This tool aims to replicate the bench test method described in ASTM F543 (2023) – Annex 3 – "Test Method for Determining the Axial Pullout Strength of Medical Bone Screws". This tool uses physics-based finite element modeling and an advanced damage and failure model to simulate foam failure during the screw pullout process. The only required input to evaluate pullout performance is a 3D Computer-Aided Design (CAD) file of the screw.

Qualified Context of Use

This computational model is used to assess the axial pullout load of metallic medical bone screws in rigid polyurethane foam of grade 20 PCF in accordance with the ASTM F543-Annex 3 standard and can be used as a surrogate to physical testing.

To be tested using the computational model, a screw must meet the following specifications:

- Must be made from metallic material suitable for surgical implant applications with a Young's modulus greater than 50 GPa.
- Pitch must be between 1.0 - 3.0 mm, core diameter between 1.8 - 4.7 mm, major diameter between 2.7 mm and 7.7 mm, and thread depth between 0.4 and 2.5 mm.
- The insertion technique for the medical screw as described in its surgical technique guide must result in close to ideal engagement between the foam material and the screw, as the modeling approach employed in this tool creates perfect thread engagement with the foam material.

Additional considerations regarding the use of Endpoint - numaScrew Virtual Pullout Test:

- This computational model can, for instance, be used to perform comparisons to a legally marketed comparator device (a device with a successful clinical history as justified by the user), for equivalence testing following screw design changes, or for identification of the worst-case scenario among different configurations of a screw system.
- If a comparator device is used, the pullout load of this comparator device should also be determined using the computational model to ensure equivalent testing conditions.
- The geometric details of the comparator device may be obtained from drawings, solid models, or any other source consistent with defining the model geometry. Engineering judgment shall be exercised to establish limits of manufacturing tolerances and the extent of model simplification. Any such judgements and simplifications and associated rationales shall be clearly documented in the test report.
- The computational model is intended to predict the pullout load of screws with complete thread purchase in the foam material. When assessing tapered screws, which have variations in thread or core diameter along their length, special attention should be given to ensure that the modeled scenario accurately reflects the real-world conditions being tested.
- Use of this model to evaluate screws with certain geometries and technological characteristics (e.g., unique thread designs, coatings, porosity, fenestrations, modularity, and geometries allowing flexibility) may lead to inaccurate pullout load predictions; therefore, use of the tool in these scenarios might not be applicable or appropriate.

Summary of Evidence to Support Qualification

The model credibility was assessed following the ASME V&V 40-2018 framework [1] and the FDA Guidance "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions" [2].

A validation study was conducted by comparing the model's predictions against experimental pullout test results. The study evaluated 18 different metallic bone screws designed by 5 manufacturers, representing a diverse range of clinical applications (Figure 1). The test samples encompassed extensive design variations, including:

- Minor diameters ranging from 1.8 to 4.69 mm
- Major diameters ranging from 2.7 to 7.7 mm
- Thread pitch ranging from 1 to 3 mm
- Tapered and cylindrical core designs
- Self-tapping and non self-tapping designs
- Titanium and stainless-steel alloys

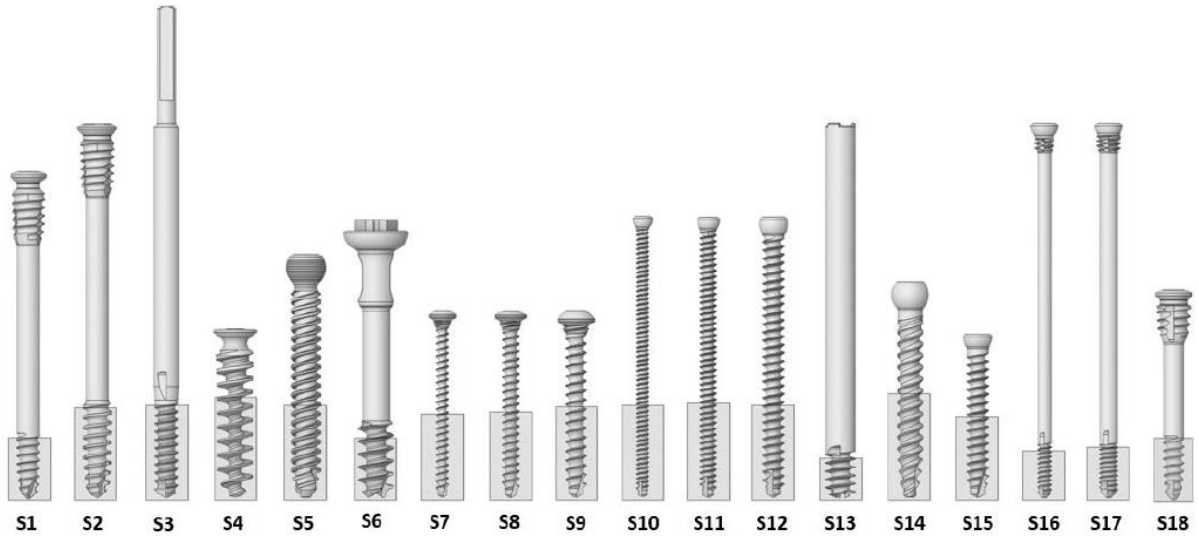

Figure 1: Metallic bone screws (S1 to S18) included in the validation study.

Each screw underwent five experimental pullout tests following ASTM F543-Annex 3 methods and was virtually replicated using the computational model. The model's predictive performance was evaluated through both quantitative and qualitative methods. Quantitatively, the analysis compared the pullout loads between simulated screw pullout tests and experimental results. Qualitatively, the assessment examined the full force-displacement curves and the foam failure patterns that occurred after pullout. Statistical analyses were used to compare pullout loads predictions against experimental data and included accuracy and precision measurements, intraclass correlation coefficient (ICC), and Spearman rank correlation coefficient (rs). Additionally, the computational model's predictive performance was benchmarked against the Chapman analytical formula [3], a published method for estimating screw axial pullout strength based on geometric features [4].

Experimental and predicted screw pullout loads are shown in Figure 2. The pullout loads for the experimental tests ranged from 285 N to 1323 N, with an average variability of ± 5.1%. The computational model demonstrated superior predictive capability with 8.0% mean absolute error (95% CI: -10.3% to 20.7%) compared to the Chapman formula's 23.2% (95% CI: -52.5% to 17.8%). Relative to experimental data, the model achieved an ICC of 0.979 and r_s of 0.985, while the Chapman formula yielded values of 0.876 and 0.873, respectively (Figure 3).

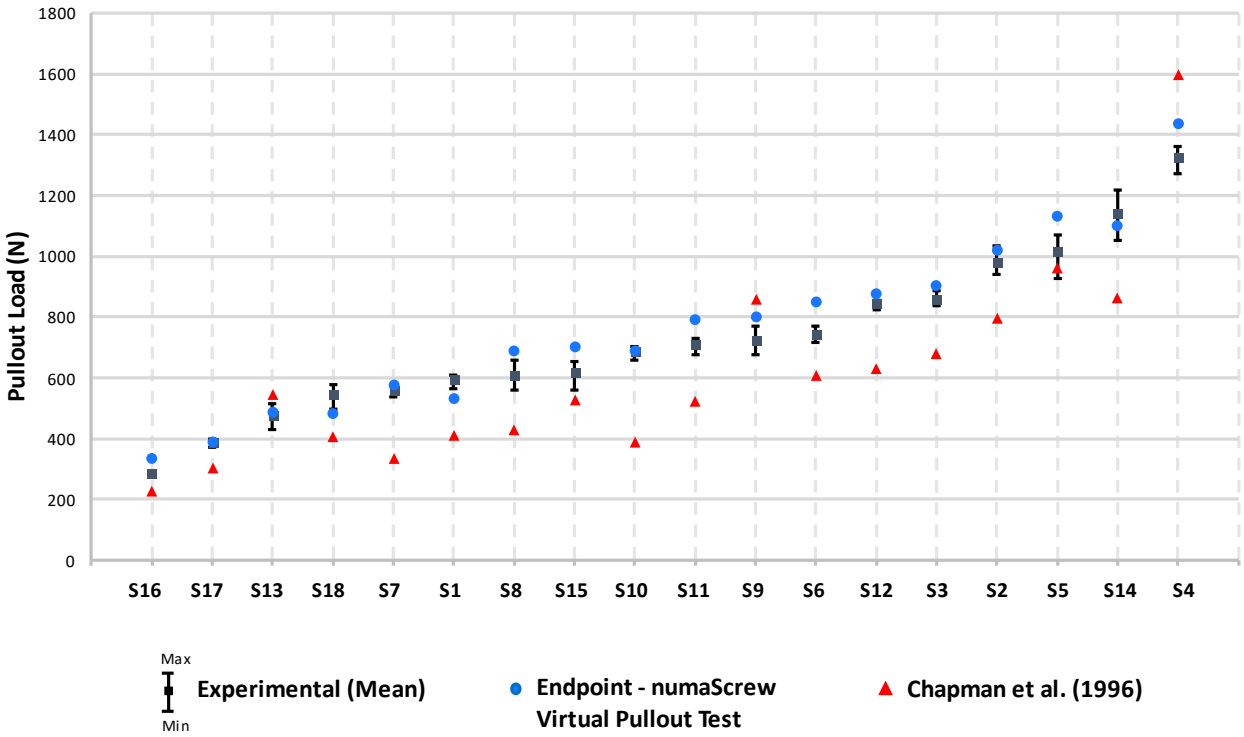

Figure 2: Experimental and predicted pullout load ranked from minimum to maximum.

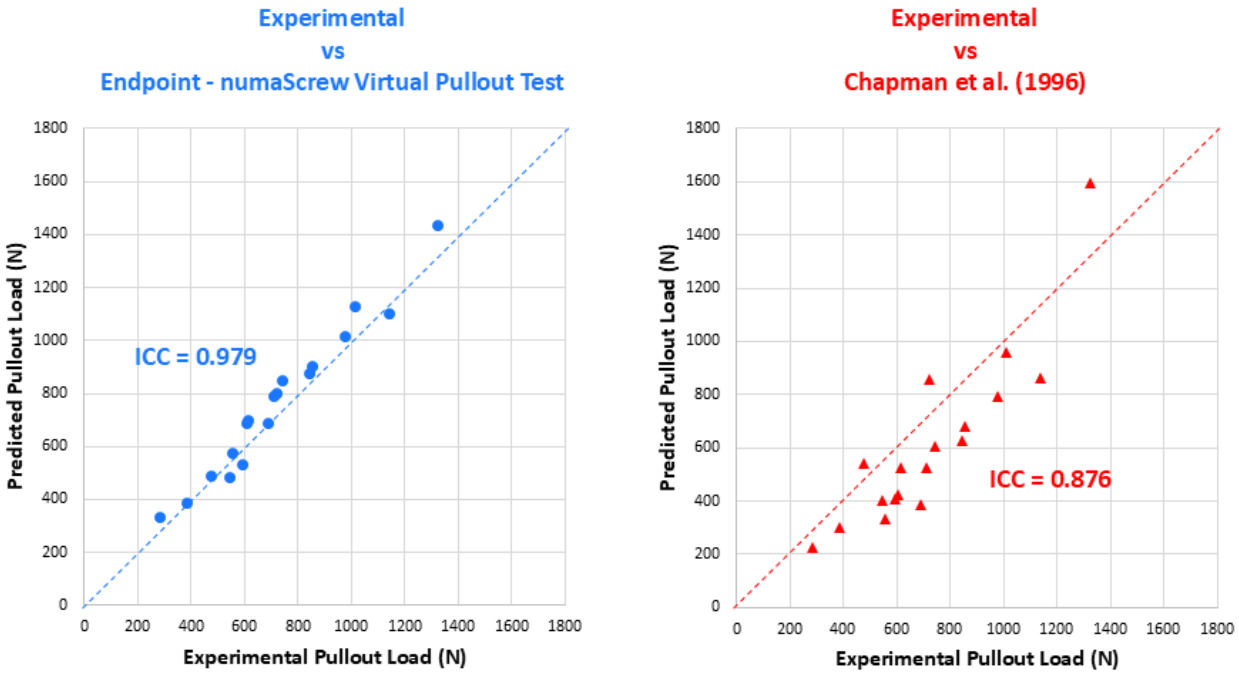

Figure 3: Pullout load predictions reliability.

Discussion of the Evidence Strength to Support Qualification

The computational model predictions of screw pullout load aligns with experimental results with a predictive reliability of 0.979 ICC compared to 0.876 ICC for Chapman equation predictions [5].The model was correlated well to experimental bench testing results [6]. Qualitative comparisons of force-displacement curves and failure patterns demonstrated the model's ability to capture the underlying physics of screw pullout. Considering the precision of the pullout load predictions, the predicted value will be reported alongside 95% confidence interval bounds derived from validation data.

Assessment of advantages/limitations of use

Advantages of using the MDDT:

- Can be used to support regulatory submissions.
- Reduces development time and costs by eliminating the need for prototyping and physical testing to evaluate screw pullout load.
- Provides measurable insight into how specific screw design features directly impact performance.
- Enables efficient evaluation of multiple screw design variations for identification of optimal configurations.
- Offers consistent testing conditions that bypass the inherent variability in foam specifications, equipment, test setup, operator, and results interpretation.

Limitations of using the MDDT:

- The model predicts pullout load of screws with ideal thread engagement in the polyurethane foam. Therefore, this tool may not accurately predict the absolute or relative pullout load of a screw with special features (e.g., taper) or surgical techniques (e.g., pilot hole larger than screw core diameter) that result in a real-world scenario where screw threads do not fully engage in substrate material.
- The tool does not account for specific techniques used for pilot hole or tap preparation and does not simulate the effects of foam compaction resulting from insertion of the screw into the foam block.
- The tool simulates screw pullout in a computational material model of 20 PCF polyurethane foam and no other foam densities. Any future changes to this computational material model form and input parameters might necessitate requalification.

Conclusions

Based on the credibility evidence, the Endpoint - numaScrew Virtual Pullout Test reliably predicts the axial pullout load of metallic bone screws in rigid polyurethane foam of grade 20 PCF in accordance with the ASTM F543-Annex 3 standard. Within the qualified context of use, Endpoint - numaScrew Virtual Pullout Test can be used as a surrogate to experimental testing.

Contact information for tool access

For access to this tool, please contact Numalogics Inc. at info@numalogics.com 4200 Boulevard Saint-Laurent, Suite #1100, Montreal, QC, Canada, H2W 2R2

More information about Endpoint - numaScrew Virtual Pullout Test is available at https://www.sawbones.com/endpoint- virtual-orthopedic-mechanical-implant-tests-fea

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References

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[2] Food and Drug Administration, “Assessing the credibility of computational modeling and simulation in medical device submissions,” *Guidance for Industry and Food and Drug Administration Staff. Silver Spring, MD, USA: Food and Drug Administration*, 2023.
[3] J. R. Chapman, R. M. Harrington, K. M. Lee, P. A. Anderson, A. F. Tencer, and D. Kowalski, “Factors affecting the pullout strength of cancellous bone screws,” *Journal of Biomechanical Engineering*, vol. 118, no. 3, pp. 391–398, 1996, doi: 10.1115/1.2796022.
[4] Food and Drug Administration, “Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway,” *Guidance for Industry and Food and Drug Administration Staff. Silver Spring, MD, USA: Food and Drug Administration*, 2024.
[5] T. K. Koo and M. Y. Li, “A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research,” *Journal of Chiropractic Medicine*, vol. 15, no. 2, pp. 155–163, 2016, doi: 10.1016/j.jcm.2016.02.012.
[6] P. Schober and L. A. Schwarte, “Correlation coefficients: Appropriate use and interpretation,” *Anesthesia and Analgesia*, vol. 126, no. 5, pp. 1763–1768, 2018, doi: 10.1213/ANE.0000000000002864.