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

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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)