January 16, 2026

Toro Neurovascular, Inc.
Ryan Walker
Co-Founder and Chief Operating Officer
470 Wald
Irvine, California 92618

Re: K252297
Trade/Device Name: Toro 88 Superbore Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 18, 2025
Received: December 19, 2025

Dear Ryan Walker:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252297

Device Name
Toro 88 Superbore Catheter

Indications for Use *(Describe)*
The Toro 88 Superbore Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared:	January 13, 2026
Primary Device Classification Name:	Catheter, Percutaneous, Neurovasculature
Secondary Device Classification Name:	Catheter, Percutaneous
Device Name:	Toro 88 Superbore Catheter
Applicant:	Toro Neurovascular, Inc. 470 Wald Irvine, CA 92618
Applicant Contact:	Ryan Walker Chief Operating Officer 657-229-1108
Regulation Number:	21 CFR 870.1250
Primary Classification Product Code:	QJP
Secondary Classification Product Code:	DQY
Regulation Medical Specialty:	Cardiovascular
510(k) Review Panel:	Neurology
Predicate Device:	TracStar LDP Large Distal Platform; Zoom 88 Large Distal Platform; Zoom 88 Large Distal Platform Support (K240948)

Device Description:
The Toro 88 Superbore Catheter is a variable stiffness, single lumen catheter designed to introduce interventional devices into the vasculature. The catheter shaft design includes stainless steel and nitinol wires and polymers of varying durometers. The catheter incorporates an internal lubricious liner to facilitate its advancement over a steerable guidewire or microcatheter. To reduce friction during manipulation, a hydrophilic coating is applied to the distal exterior section of the catheter shaft. A single radiopaque tip marker provides visualization under fluoroscopy. The proximal end of the catheter includes a hub with Luer lock. The catheter is supplied sterile, for single use only.

Indications for Use Statement:
The Toro 88 Superbore Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Comparison with the Predicate Device:

Device Attribute	TracStar Large Distal Platform Zoom 88 Large Distal Platform Zoom 88 Large Distal Platform Support (K240948)	Toro 88 Superbore Catheter (K252297)
Indications for Use Statement	The TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The Zoom 88 Large Distal Platform and Zoom 88 Large Distal Platform Support are indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Toro 88 Superbore Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Primary Classification Product Code	QJP	Same as K240948
Secondary Classification Product Code	DQY	Same as K240948
Regulation Number	21 CFR 870.1250	Same as K240948
Regulation Medical Specialty	Cardiovascular	Same as K240948
Review Panel	Neurology	Same as K240948
Design Feature(s)		
Tip	Beveled Distal Edge, Soft, Flexible, Atraumatic	Straight Distal Edge, Soft, Flexible, Atraumatic
Dimensional Specifications		
Proximal Inner Diameter	0.088”	Same as K240948
Proximal Outer Diameter	0.110”	0.108”
Distal Inner Diameter	0.088”	Same as K240948
Distal Outer Diameter	0.106”	Same as K240948
Effective Length	TracStar LDP: 80 – 105 cm Zoom 88 LDP: 110 cm Zoom 88 LDP Support: 100 cm	118 cm
Materials		
Distal Catheter Shaft	Reinforced with metals and polymers	Same as K240948
Proximal Catheter Shaft	Reinforced with metals and polymers	Same as K240948
Coating	Hydrophilic coating	Same as K240948

Device Attribute	TracStar Large Distal Platform Zoom 88 Large Distal Platform Zoom 88 Large Distal Platform Support (K240948)	Toro 88 Superbore Catheter (K252297)
Materials	Commonly used medical grade plastics and metals with hydrophilic coating	Same as K240948
Accessories and Packaging		
Accessories	Rotating Hemostasis Valve	Split Introducer Sheath
Packaging Configuration	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.	The catheter is placed in a protective polyethylene tube, mounted with split introducer sheath onto a high-density polyethylene backer card, placed into a pouch, sealed, and labeled. The sealed pouch and Instructions for Use are placed inside a labeled shelf carton.
Shelf Life		
Shelf Life	36 Months	12 Months
Sterility		
Sterilization Method	Ethylene Oxide	Same as K240948
Sterility Assurance Level (SAL)	10^{-6}	Same as K240948

Biocompatibility:

Test	Test Method	Acceptance Criteria	Results
L929 MEM Elution Test – ISO	ISO 10993-5:2009	To be non-cytotoxic, the device must achieve a Grade of 2 or lower.	Pass: Non-cytotoxic.
Kligman Maximization Test – ISO	ISO 10993-10:2021	Using the scoring system of Magnusson and Kligman, the device must achieve a Grade < 1.	Pass: Non-sensitizing.
Intracutaneous Injection Test – ISO	ISO 10993-23:2021	To be a non-irritant, the mean score difference between the test device and vehicle control must be ≤ 1.0.	Pass: Non-irritant.
Systemic Injection Test – ISO	ISO 10993-11:2017	The Toro 88 Superbore Catheter passes if none of the animals injected with device extracts show a significantly greater biological response than the control animals.	Pass: Non-toxic.
Rabbit Pyrogen Test (Material-Mediated) – ISO	ISO 10993-11:2017 USP <151>	To meet pyrogen absence requirements, no rabbit should show a temperature increase of 0.5°C or more above baseline.	Pass: Non-pyrogenic.
Rabbit Blood Hemolysis Test (Direct Method) – ASTM	ASTM F756-17 ISO 10993-4:2017	To be non-hemolytic, the hemolytic index must be < 2%.	Pass: Non-hemolytic.
Rabbit Blood Hemolysis Test (Indirect Method) – ASTM	ASTM F756-17 ISO 10993-4:2017	To be non-hemolytic, the hemolytic index must be < 2%.	Pass: Non-hemolytic.
SC5b-9 Complement Activation Test (Direct Contact) – ISO	ISO 10993-4:2017	To be a non-activator of the complement system, there should be no statistically significant increase between SC5b-9 concentrations in the plasma exposed to the device and that of the plasma exposed to the negative control article, the untreated control, and/or a commercially available device.	Pass: Non-activator of the complement system.
Thrombogenicity Study in Dogs – ISO	ISO 10993-4:2017	The Toro 88 Superbore Catheter is non-thrombogenic if thrombus formation is comparable to or lesser than a commercially available device.	Pass: Comparable.
Partial Thromboplastin Time Test (Direct Contact) – ASTM	ASTM F2382-18 ISO 10993-4:2017	The Toro 88 Superbore Catheter is non-reactive if the PTT% is not significantly different from the untreated control, negative control, and/or a commercially available device.	Pass: No effect on coagulation of human plasma.
Platelet and Leukocyte Count Test (Direct Contact) – ASTM	ASTM F2888-19 ISO 10993-4:2017	The Toro 88 Superbore Catheter will be considered comparable to the reference article if the platelet count of the test article is within 80-120% of the reference article.	Pass: No effect on platelet and leukocyte concentrations.

Packaging:

Test	Test Method Summary	Result
Visual Inspection	The Toro 88 Superbore Catheter was evaluated per ASTM F1886/F1886M-16.	Pass
Seal Width	The Toro 88 Superbore Catheter was evaluated by measuring pouch seals to verify sufficient seal width to ensure sterility after distribution.	Pass
Bubble Leak	The Toro 88 Superbore Catheter was evaluated per ASTM F2096-11 (2019).	Pass
Seal Strength	The Toro 88 Superbore Catheter was evaluated per ASTM F88/F88M-23.	Pass

Sterilization:

Test	Test Method Summary	Result
Ethylene Oxide Residual	The Toro 88 Superbore Catheter was evaluated per ISO 10993-7:2008/Amd 1:2019.	Pass
Ethylene Chlorohydrin Residual	The Toro 88 Superbore Catheter was evaluated per ISO 10993-7:2008/Amd 1:2019.	Pass
Bacterial Endotoxin Testing	The Toro 88 Superbore Catheter was evaluated per AAMI/ANSI ST72:2019 and USP-<85>.	Pass

Performance Data – Bench:

Test	Test Method Summary	Result
Design Verification		
Dimensional Verification	The Toro 88 Superbore Catheter was evaluated to ensure the dimensional specifications were met for inner diameter, outer diameter, coating length, and working length.	Pass
Visual Inspection	The Toro 88 Superbore Catheter was evaluated to ensure the device met the surface requirements per ISO 10555-1:2023, §4.7.	Pass
Simulated Use	The Toro 88 Superbore Catheter was evaluated to verify the performance of the device as it relates to device preparation, maneuverability, durability, compatibility, burst pressure, and torque strength.	Pass
Tensile Strength	The Toro 88 Superbore Catheter was tested in accordance with ISO 10555-1:2023, Annex B to ensure the device has sufficient strength to withstand tensile forces throughout a procedure.	Pass
Coating Lubricity	The Toro 88 Superbore Catheter was evaluated to ensure the frictional forces are comparable to or less than the predicate device.	Pass

Test	Test Method Summary	Result
Particulate Evaluation	The Toro 88 Superbore Catheter was evaluated to ensure the particulate count and size distribution (≥10µm, ≥25µm, and ≥50µm) are comparable to or less than the predicate device.	Pass
Coating Integrity	The Toro 88 Superbore Catheter was evaluated post-simulated use to ensure the coating was free of defects that contribute to unacceptable particulate generation .	Pass
Kink Resistance	The Toro 88 Superbore Catheter was evaluated to ensure the catheter shaft does not kink when navigating anatomically relevant bends with varying radii.	Pass
Liquid Leakage	The Toro 88 Superbore Catheter was evaluated to ensure the device remains leak free when tested in accordance with ISO 10555-1:2023, Annex C.	Pass
Flowrate	The Toro 88 Superbore Catheter was evaluated to ensure the flowrate of the device was comparable to the predicate device when tested in accordance with ISO 10555-1:2023, Annex E.	Pass
Distal Tip Stiffness	The Toro 88 Superbore Catheter was evaluated to ensure the distal tip stiffness of the device was comparable to or lower than the predicate device.	Pass
Radiopacity	The Toro 88 Superbore Catheter was evaluated to ensure the marker band is radiopaque.	Pass
Small-Bore Connectors	The Toro 88 Superbore Catheter was evaluated to ensure the dimensional and performance requirements were met per ISO 80369-7:2021 and ISO 80369-20:2024.	Pass
Compatibility	The Toro 88 Superbore Catheter was evaluated to ensure it is compatible with syringes and contrast media.	Pass
Air Leakage	The Toro 88 Superbore Catheter was evaluated to ensure the device remains leak free when tested in accordance with ISO 10555-1:2023, Annex D.	Pass
Static Burst Pressure	The Toro 88 Superbore Catheter was tested in accordance with ISO 10555-1:2023, Annex F to ensure the device does not burst under pressure that could be seen when performing contrast injections.	Pass

Test	Test Method Summary	Result
Torque Strength	The Toro 88 Superbore Catheter was evaluated to ensure the torque strength of the device was comparable to commercially available devices.	Pass
Design Validation and Usability Engineering		
Design Validation	The Toro 88 Superbore Catheter was evaluated to validate the performance of the device, including its packaging and labeling, with intended users.	Pass
Usability Engineering	The Toro 88 Superbore Catheter was evaluated for usability per IEC 62366-1:2015/Amd 1:2020.	Pass

Performance Data – Animal:
A determination of substantial equivalence is based upon successful completion of bench performance testing.

Performance Data – Clinical:
A determination of substantial equivalence is based upon successful completion of bench performance testing.

Conclusion:
The Toro 88 Superbore Catheter is substantially equivalent to the TracStar Large Distal Platform, Zoom 88 Large Distal Platform, and Zoom 88 Large Distal Platform Support based on the same intended use and similar technological characteristics. The differences do not raise new or different questions of safety and effectiveness. The successful completion of non-clinical testing supports that the device meets the design specifications and performs as intended.