June 29, 2022

Terumo Medical Products (Hangzhou) Co., Ltd.
% Qing Liu
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K220934
Trade/Device Name: RADIFOCUS Torque Device
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, PTL
Dated: March 31, 2022
Received: March 31, 2022

Dear Qing Liu:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220934

Device Name
RADIFOCUS Torque Device

Indications for Use *(Describe)*
RADIFOCUS Torque Device is intended to facilitate guidewire manipulation during interventional procedures.

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

A. SUBMITTER INFORMATION (807.92(a)(1))

Prepared by: Qing Liu
Regulatory Affairs Specialist
Terumo Medical Corporation
Tel. (908) 842-9016
Fax (410) 398-6079

Prepared for: ***Owner/Operator***
Terumo Medical Products (Hangzhou) Co., Ltd.
M4-9-5 Hangzhou Economic and Technological Development Zone, Hangzhou, 310018, People's Republic of China
Registration Number: 3004102031

Manufacturer and Sterilization Facility (Applicant)
Terumo Medical Products (Hangzhou) Co., Ltd.
M4-9-5 Hangzhou Economic and Technological Development Zone, Hangzhou, 310018, People's Republic of China
Registration Number: 3004102031

Contact Person: Qing Liu
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Ave, Suite 320
Somerset, NJ 08873, USA
Tel. (908)842-9016
Fax (410) 398-6079
E-mail: kyo.ryu@terumomedical.com

Date prepared: 6/29/2022

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	RADIFOCUS Torque Device
Common Name:	Torque Device
Classification Name:	Catheter Guide Wire
Classification Panel:	Neurology, Cardiovascular
Regulation:	21 CFR 870.1330
Product Code:	Primary: MOF, Secondary: PTL
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device to which substantial equivalence is claimed is:

K910969 – TORQUE DEVICE FOR A GUIDE WIRE, manufactured by Terumo Corporation, Japan.

D. DEVICE DESCRIPTION (807.92(a)(4))

RADIFOCUS Torque Device is a supportive device intended to facilitate guide wire manipulation during interventional procedures.

This product consists of a cap that screws onto the main body of the device (handle) to apply a clamping force on the guide wire. The cap is made of polypropylene and the handle is made of polyoxymethylene. The torque device can be used for the guide wires with diameters of 0.010” to 0.038”. RADIFOCUS Torque Device is sterilized with ethylene oxide.

E. INDICATIONS FOR USE (807.92(a)(5))

RADIFOCUS Torque Device is intended to facilitate guidewire manipulation during interventional procedures.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS (807.92(a)(6))

RADIFOCUS Torque Device, the subject of this 510(k), is substantially equivalent in its intended use, technology, principle of operation, materials, and performance to the TORQUE DEVICE FOR A GUIDE WIRE, manufactured by Terumo Corporation, Japan (K910969).

The comparison of the technological characteristics is summarized in the table below.

Device Characteristic	**Subject Device:** RADIFOCUS Torque Device (K220934)	**Predicate Device:** TORQUE DEVICE FOR A GUIDE WIRE (K910969)
Manufacturer	Terumo Medical Products (Hangzhou) Co., Ltd.	Terumo Corporation
Operation Principle	Manual	Same
Design / Construction	This product consists of a cap and a handle with a clamp.	Same
Materials	• Cap – Polypropylene • Handle –Polyoxymethylene	Same
Package	• Unit pouch • Shelf box • Large shelf box	Same
Specifications	Compatible with guide wires that range from 0.010" (0.26 mm) to 0.038" (0.97 mm) in diameter.	Compatible with guide wires that range from 0.014" (0.36 mm) to 0.038" (0.97 mm) diameter.
Sterilization	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same
Disposable, Single Use	Yes	Same

G. NON-CLINICAL TESTS (807.92(b)(1))

Performance

Performance testing was conducted to ensure the RADIFOCUS Torque Device met the predetermined specifications throughout the shelf life, to verify conformity to the acceptance criteria, and demonstrate substantial equivalence to the predicate device.

No new issues of safety and effectiveness were raised with the testing performed. The following performance tests were performed on the RADIFOCUS Torque Device:

Performance Test	Results
Appearance	Meets acceptance criteria
Fixed strength of guide wire	Meets acceptance criteria
Fixed strength of cap	Meets acceptance criteria
Fixable dimension	Meets acceptance criteria
Guide wire damage	Meets acceptance criteria
Collet release	Meets acceptance criteria
Torque slip force	Meets acceptance criteria

The RADIFOCUS Torque Device tested met the predetermined acceptance criteria. Based on the results of the performance testing, the subject RADIFOCUS Torque Device is substantially equivalent to the predicate.

Biocompatibility

The RADIFOCUS Torque Device is a non-tissue contacting medical device, therefore, this 510(k) submission does not include biocompatibility data.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014*, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*.

The sterilization process was validated utilizing the overkill half cycle approach to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Post sterilization, RADIFOCUS Torque Device product meets the maximum residue limits in accordance with ISO 10993-7: 2008.

The maximum allowable residue levels are:

- Ethylene oxide (EtO): 4 mg/device
- Ethylene chlorohydrin (ECH): 9 mg/device

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971, and it was determined that there were no new issues of safety or effectiveness.

H. CLINICAL TESTS (807.92(b)(2))

This 510(k) submission does not include data from clinical tests, which were not deemed necessary.

I. CONCLUSION (807.92(b)(3))

In summary, the RADIFOCUS Torque Device, subject of this 510(k), is substantially equivalent in its intended use, technology, principle of operation, materials, and performance to the primary predicate device K910969 – TORQUE DEVICE FOR A GUIDE WIRE manufactured by Terumo Corporation, Japan.