April 6, 2022

Truvic Medical Inc.
% Semih Oktay
President
CardioMed Device Consultants, LLC
1783 Forest Drive, Suite 254
Annapolis, Maryland 21401

Re: K214114
Trade/Device Name: Prodigy™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: March 7, 2022
Received: March 9, 2022

Dear Semih Oktay:

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,

For

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K214114

Device Name
Prodigy™ Thrombectomy System

Indications for Use *(Describe)*
The Prodigy™ Thrombectomy System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

Not for use in the coronaries, pulmonary vasculature, or the neurovasculature

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
[as required by 21 CFR 807.92(c)]

TRUVIC

1359 Dell Avenue Campbell, CA 95008 USA

TRUVIC Prodigy™ Thrombectomy System

510(k) K214114

DATE PREPARED:	30 March 2022
APPLICANT	Truvic Medical, Inc. 1359 Dell Avenue Campbell, CA 95008 USA
CONTACT	Michael Buck Chief Executive Officer Tel: (650) 842-0240 e-mail: mbuck@truvic.com
TRADE NAME:	Prodigy™ Thrombectomy System
DEVICE CLASSIFICATION:	Class 2 per 21 CFR §870.5150
CLASSIFICATION NAME:	Catheter, Embolectomy
PRODUCT CODE	QEW
PREDICATE DEVICES:	Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) K142870

Intended Use / Indications for Use

The Prodigy™ Thrombectomy System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.

Not for use in the coronaries, pulmonary vasculature, or the neurovasculature.

DEVICE DESCRIPTION:

The Prodigy™ Thrombectomy System is designed to remove thrombus from the vasculature using aspiration. The Prodigy™ Thrombectomy System is comprised of several components including:

- Prodigy™ Catheter
- Prodigy™ Twist
- Prodigy™ Hotshot™ Controller
- TRUVIC Generator
- TRUVIC Canister
- TRUVIC Tubeset

The single-lumen Prodigy™ Catheter targets aspiration from the TRUVIC Generator directly to the thrombus. The wire-based Prodigy™ Twist utilizes a soft, flexible polymeric tip to facilitate thrombus removal through the Prodigy™ Catheter as needed. The Prodigy™ Catheter is available in multiple diameters and both the Prodigy™ Catheter and Prodigy™ Twists are available in multiple effective lengths and are visible under fluoroscopy via radiopaque marker bands.

The Prodigy™ Hotshot™ Controller connects the Prodigy™ Catheter to the TRUVIC Generator and provides the user with the ability to control aspiration flow and visualize the extracted thrombus.

COMPARISON WITH PREDICATE DEVICE:

The subject device Prodigy™ Thrombectomy System and the predicate Penumbra INDIGO System have the same intended use, operating principle, design concept, materials, and sterilization processes. Both the subject and predicate systems utilize a catheter and wire-based device to facilitate thrombus removal, and both employ a continuous aspiration pump in this extraction function.

Table 1. Summary of Comparison Between Subject and Predicate Device

		Subject	**Predicate**
Name of Device		**Prodigy™ Thrombectomy System**	**INDIGO Aspiration System**
Manufacturer		Truvic Medical, Inc.	Penumbra, Inc.
510(k) #		K214114	K142870
Indications for Use		The Prodigy™ Thrombectomy System is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.	The Penumbra Embolectomy Aspiration System (INDIGO™ Aspiration System) is intended for the removal of fresh, soft emboli and thrombi from vessels of the peripheral arterial and venous systems.
		Not for use in the coronaries, pulmonary vasculature, or the neurovasculature.	Not for use in the coronaries or the neurovasculature.
Catheter Shaft Characteristics	Device Design	Intravascular catheter	Intravascular Embolectomy catheter
	Catheter Size(s)	5F, 6F, 8F	3F, 5F, 6F, 8F
	Useable Length(s)	50cm, 90cm, 137cm, 160cm	85cm, 115cm, 132cm, 135cm, 150cm
Radiopaque Markers		90%, Platinum, 10% Iridium	90%, Platinum, 10% Iridium
Hydrophilic coating		Yes	Yes
Hydrophobic coating		No	No
Sterilization Method		Ethylene Oxide (EO)	Ethylene Oxide (EO)

	Subject	Predicate
Thrombus Removal Assist Device	**Twist**	**Separator**
Size / Length	5F, 177cm 6F, 154cm 8F, 67cm 8F, 107cm	3F, 190cm 5F, 175cm 6F, 175cm 8F, 150cm
User Control	**Prodigy™ Hotshot™ Controller** On/Off and Vent	**INDIGO Aspiration Tubing Valve** On/Off
User Control Patient Contacting?	No	No
Material Comparison		
Materials for Catheter, Twist and User Control	Commonly used medical grade plastics and metals	Commonly used medical grade plastics and metals

NON-CLINICAL TESTING / PERFORMANCE DATA:

Non-clinical laboratory testing was performed on the Prodigy™ Thrombectomy System to assure compliance with all pre-specified, clinically relevant acceptance criteria and to determine substantial equivalence as it relates to the intended use. The following testing/assessments were successfully performed:

- Visual and Dimensional Verification
- Twist Distal Tip Stiffness Verification
- Kink / Bend / Flex Verification
- Tensile / Bond Strength Verification
- Positive Pressure / Liquid Leak Verification
- Vacuum / Air Leak Verification
- Lumen Integrity Verification
- Torque Strength Verification
- Burst Pressure Verification
- Fluoroscopy Validation (Visibility test)
- Simulated Use Performance Validation
- Corrosion Resistance Testing
- Coating Integrity Testing
- Acute Particulate Testing
- Drop Testing Verification
- Fatigue Testing Verification
- Component Actuation Force Testing Verification

The in vitro bench tests demonstrated that the Prodigy™ Thrombectomy System met all acceptance criteria and performed similarly to the predicate device. Performance data demonstrate that the Prodigy™ Thrombectomy System devices function as intended and has a safety and effectiveness profile that is similar to the predicate devices.

BIOCOMPATIBILITY:

Testing was performed to assess biocompatibility of the Prodigy™ Thrombectomy System patient-contacting components. The following tests were successfully performed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
- Complement Activation
- In-Vivo Thrombogenicity (from GLP animal study)

Adherence to the test methodologies and standards was maintained in all biocompatibility testing described. Each of the biocompatibility tests defined above passed. There was no evidence of toxicity, sensitization, or irritation. Testing found samples to be non-hemolytic, non-activator, and non-pyrogenic. All testing was conducted in compliance with GLP regulations, 21 CFR Part58.

***IN-VIVO* GLP PRE-CLINICAL TESTING / PERFORMANCE DATA:**

A GLP animal study was performed to assess the acute and chronic safety and performance of the Prodigy™ Thrombectomy System as compared to the predicate. *In-vivo* thrombogenicity was also assessed.

There were no complications in Prodigy™ Thrombectomy System device preparation or performance and no vascular injuries were observed. All treated vessels were free from thrombus formation in both acute and chronic cohorts. All acceptance criteria passed. The Truvic Prodigy™ Thrombectomy System was deemed equivalently safe as compared to the predicate in all measured assessments.

CONCLUSION:

The Truvic Prodigy™ Thrombectomy System has the intended use and the same or similar technological characteristics such as components, design, materials, sterilization method, and operating principles as the predicate device. Performance data demonstrates that the device functions as intended. The non-clinical and *in-vivo* pre-clinical tests demonstrate that the Prodigy™ Thrombectomy System is equivalently safe and effective in achieving its intended use as the predicate.

Therefore, the Truvic Prodigy™ Thrombectomy System is substantially equivalent to the predicate device.