October 22, 2025

Intervene
% Mark Smutka
Regulatory Consultant
Mark Smutka
6149 Valley Glen Drive
San Jose, California 95123

Re: K251185
Trade/Device Name: Recana Thrombectomy Catheter System (FG014, FG015, FG016, FG017, FG018, FG019, FG020)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW, KRA
Dated: April 16, 2025
Received: September 18, 2025

Dear Mark Smutka:

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,

GREGORY W. O'CONNELL -S

Digitally signed by GREGORY W. O'CONNELL -S
Date: 2025.10.22 13:32:13 -04'00'

Gregory O'Connell
Assistant Director
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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)*
K251185

Device Name

Recana Thrombectomy Catheter System (FG014. FG015, FG016, FG017, FG018, FG019, FG020)

Indications for Use *(Describe)*

The Recana Thrombectomy Catheter System is indicated for:
• The non-surgical removal of thrombi and emboli from veins.
• Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vein.

The Recana Thrombectomy Catheter System is indicated for use in peripheral venous 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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Recana Thrombectomy Catheter System 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K251185

Applicant Information:

Date Prepared:	April 18, 2025
Name:	InterVene, Inc.
Address:	2684 Middlefield Road, Suite E Redwood City, CA 94063
Contact Person:	Mark Smutka, Consultant msmutka@comcast.net
Mobile Number:	(408) 981-7531

Device Information:

Device Trade Name:	Recana Thrombectomy Catheter System (FG014. FG015, FG016, FG017, FG018, FG019, FG020)
Common Name:	Recana Thrombectomy Catheter System
Classification Name(s):	Peripheral Mechanical Thrombectomy With Aspiration
Product Code/ Regulation:	QEW / 21 CFR 870.5150; KRA / 21 CFR 870.1210
Classification:	Class II

Predicate Device:
K223609, Inari RevCore Thrombectomy Catheter

Reference Device:
K212632, Inari ClotTriever Thrombectomy System

Subject Device Description

The Recana Thrombectomy Catheter System is designed to remove thrombus and emboli from native vessels or stented veins. The system is comprised of the debulking catheter, collection basket(s) with delivery sheaths, and a family of sheaths. Together, the Recana Thrombectomy Catheter System functions to capture and remove obstructive / occlusive thrombus from the venous vasculature.

The debulking catheter utilizes an adjustable diameter stainless steel coring element to remove thrombus from the venous vasculature. Handle controls enable expansion and collapse of the coring element to achieve the desired working diameter. The debulking catheter is 0.035" guidewire and 0.060" basket shaft compatible and provides a working length of 80cm.

18mm and 30mm Collection basket(s) are self-expanding nitinol wire-form and braided structures designed to ensure capture and removal of thrombi and emboli. The basket shaft has a 0.035" guidewire compatible lumen for over the wire delivery through a 9Fr Delivery Sheath with a working length of 95cm.

Sheaths for introduction of the debulking catheter and collection baskets into the vasculature and for the recapture and removal of thrombi and emboli via the collection basket(s) are offered in four (4) size configurations (13Fr x 30cm, 13Fr x 90cm, 16Fr x 30cm, and 16Fr x 90cm) providing optionality based on access vessel size and location.

Subject Device Indications for Use
The Recana Thrombectomy Catheter System is indicated for:

- The non-surgical removal of thrombi and emboli from veins.
- Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vein.

The Recana Thrombectomy Catheter System is indicated for use in the peripheral venous vasculature.

Recana Thrombectomy Catheter System 510(k) Summary

Substantial equivalence of the InterVene Recana Thrombectomy Catheter System when compared to the predicate device, Inari RevCore Thrombectomy Catheter (K223609), and reference device, Inari ClotTriever Bold Thrombectomy Catheter (K212632) was established through consideration of:

- Indications for Use
- Design
- Principles of operation with similar technological characteristics
- Labeling/packaging materials and configuration
- Sterilization of devices

The InterVene Recana Thrombectomy Catheter System as well as the predicate and reference devices are the same or similar with respect to the aspects above.

All of the devices are the same in the basic principles of operation and similar technological characteristics. Each device functions to restore flow in the veins via mechanical removal of obstructive and/or occlusive thrombi and emboli. All are placed in the selected treatment vessels percutaneously through introducer sheaths and positioned beyond the obstructive and/or occlusive material then utilize their coring elements to engage and remove the thrombi and emboli.

Comparison of Subject Device to Predicate Device and Reference Device:

Characteristic	Subject	Predicate Device	Reference Device	Comparison
Name	InterVene Recana Thrombectomy Catheter System	Inari RevCore Thrombectomy Catheter	Inari ClotTriever Bold Thrombectomy Catheter	N/A
Regulation Number	21 CFR 870.5150	21 CFR 870.5150	21 CFR 870.5150	Same
Regulatory Class	Class II	Class II	Class II	Same
Product Code	QEW	QEW	QEW	Same
510(k) Number	N/A	K223609	K212632	N/A

Indications for Use	The Recana Thrombectomy Catheter System is indicated for: • The non-surgical removal of thrombi and emboli from veins. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a vein. The Recana Catheter System is indicated for use in the peripheral venous vasculature	The RevCore Thrombectomy Catheter is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The RevCore Thrombectomy Catheter is intended for use in the peripheral vasculature.	The ClotTriever BOLD Catheter is indicated for: • The non-surgical removal of thrombi and emboli from blood vessels. • Injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. The ClotTriever BOLD Catheter is intended for use in the peripheral vasculature including deep vein thrombosis (DVT).	The Indications for Use are identical relative to overall thrombi and emboli removal. The Recana Thrombectomy Catheter System indications are for veins and does not include coronary vessels or arteries. All other indications are unchanged.
Device Features	The Recana Thrombectomy Catheter System is a single-use, sterile, over the wire, minimally invasive medical device designed to remove thrombi and emboli from stented and non-stented segments in veins. The Recana Thrombectomy System	The RevCore Thrombectomy Catheter is a single-use, sterile, over the wire catheter used for the minimally invasive treatment of thromboemboli in the peripheral vasculature, and within venous stents. The RevCore Thrombectomy Catheter consists of a distal laser-cut	The ClotTriever Thrombectomy System is a single-use, sterile medical device designed to remove thrombi and emboli from the peripheral vasculature. The ClotTriever Thrombectomy System consists of the ClotTriever Catheter, ClotTriever BOLD	The Recana Thrombectomy System includes system components for tissue liberation (Debulking Catheter) and sheaths for introduction/removal as well as capture / removal of thrombus tissue (Collection Baskets).

	consists of the Recana Debulking Catheter, Recana 13 Fr and 16 Fr Sheaths both offered in 30cm and 90cm lengths, and Recana Collection Baskets in 18mm and 30mm diameters, each packaged separately. The Recana Debulking Catheter is comprised of coaxial braid reinforced polymeric shafts, a distal size selectable coring element, and a proximal handle with controls for coring element diameter adjustment. 18mm and 30mm Collection basket(s) are self-expanding nitinol wire-form and braided structures designed to collect and remove thrombotic material from the vasculature. Sheaths enabling introduction and removal of the debulking catheter and collection basket(s)	nitinol coring element, three coaxial catheter shafts (inner, middle, and outer), and a handle with a diameter control knob. The proximal handle controls the expansion and collapse of the coring element via the handle knob. The middle and inner shaft constrains the coring element prior to deployment. To aid in fluoroscopic visualization, the distal tip is radiopaque, and a radiopaque tip is located on the outer catheter to identify the distal end of the outer catheter. The RevCore is commonly known to utilize Protrieve Sheaths for access and collection as well as additional devices such as the ClotTriever and/or FlowTriever to capture and collect material thrombus by the device.	Catheter, ClotTriever 13 Fr and 16 Fr Sheaths, and Protrieve Sheath, each packaged separately. The ClotTriever BOLD Catheter is comprised of reinforced polymeric coaxial shafts terminating in an expandable coring element and thrombus collection bag. Three ports terminating in two stopcocks and a luer lock connection are provided for de-airing the catheter shafts. To aid in fluoroscopic visualization, the ClotTriever Catheter, ClotTriever BOLD Catheter, ClotTriever Sheaths, and Protrieve Sheath have radiopaque distal tips.	The Recana Thrombectomy System principle features are the same as those present in the predicate and reference device.

	from the vasculature are offered in four (4) size configurations (13Fr x 30cm, 13Fr x 90cm, 16Fr x30cm, and 16Fr x 90cm). To aid in fluoroscopic visualization, the Recana Catheter System contains radiopaque features on each of its components (debulking catheter, sheaths, and collection baskets). Port(s) are integrated into and/or flush tool accessories are provided with the system components for de-airing.			
Principles of Operation	The Debulking Catheter coring element is composed of stainless steel and the diameter is manually controlled by a knob in the handle. The Debulking Catheter coring element is retracted through the	The coring element is composed of self-expanding nitinol and the diameter is manually controlled by a knob in the handle. The coring element is retracted through the vessel to engage and remove	The coring element is composed of self-expanding nitinol and the diameter is manually controlled by a plunger in the handle. The coring element is retracted axially through the vessel to engage and	The principles of operation are similar between the Recana Thrombectomy System and the predicate (RevCore) as well as reference device (ClotTriever).

	vessel to engage and selectively remove thrombus and emboli. Tissue removal is achieved by manual rotational and axial motion of the coring element. Access sheaths enabling introduction and removal of the debulking catheter and collection basket(s) from the vasculature are offered in four size and length configurations. The device can be removed from the vessel through the introducer sheath. The thrombus and emboli is captured in then collection basket(s) which may be removed through the introducer sheath.	thrombus and emboli. Tissue liberation is achieved by manual rotational and axial motion of the coring element. The device and captured clot are removed from the vessel through the introducer sheath.	remove thrombus and emboli. The device and captured clot can then be removed from the vessel through the introducer sheath.	Each has a coring element that can be expanded and collapsed by the user to achieve the desired working diameter in order to engage, and remove thrombus and emboli. Engagement of the target treatment site is controlled by the user and does not introduce any new or increased risks (relative to the predicate or reference device) for engaging nearby vessels, arteries, or structures such as organs, etc. The collection basket features (Recana Thrombectomy System and ClotTriever Bold) are similar and allow for positive capture and removal of thrombi and emboli.

Reusable	Single-Use and Disposable	Single-Use and Disposable	Single-Use and Disposable	Same
Power Source	Manually operated	Manually operated	Manually operated	Same
Radiopaque	Yes	Yes	Yes	Same
Packaging Configuration	Single device packaged in Tyvek pouch on card within shelf box	Single device packaged in Tyvek pouch on tray within shelf box	Single device packaged in Tyvek pouch on tray within shelf box	Same
Sterilization	Ethylene Oxide SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	Ethylene Oxide SAL 10^{-6}	Same
Minimum vessel treatment size	≥6mm	6mm	6mm	Same
Maximum Coring Element Size	12 mm	24 mm	16 mm	The Recana Thrombectomy Catheter System coring element was designed in consideration of the targeted veins and does not exceed the maximum size of the coring elements of the predicate or reference device.
Access Site	Femoral or Popliteal Veins	Femoral, Popliteal or Jugular Vein	Femoral, Popliteal or Jugular Vein	The Recana Thrombectomy Catheter System may only be utilized via femoral or

				popliteal venous access whereas the ClotTriever and RevCore can also utilize jugular access. Use via femoral or popliteal access eliminates advancing system elements through the jugular vein, superior vena cava and through the right atrium of the heart. As a result, the potential risk of embolic events caused by directly retrieving system devices and thrombus material through or near the heart is reduced.
Coring Element Material	Stainless Steel	Nitinol	Nitinol	The Recana Thrombectomy Catheter System coring element is constructed of Stainless Steel which is commonly utilized in other medical devices including venous interventional devices.

Device OD	13Fr	12Fr	12Fr	The Recana Thrombectomy Debulking Catheter has a nominally larger OD than the labeled OD of the predicate and reference device. The Recana Thrombectomy Debulking Catheter is compatible with sheaths 13Fr or larger which are commonly utilized in venous interventional procedures.
Working Length	80cm	80cm	80cm	Same
Guidewire Compatibility	.035”	.035”	.035”	Same

Table 1 - Comparison between subject and predicate device

Testing Completed
The following design verification and validation testing was performed and successfully completed on the Recana Thrombectomy Catheter System:

- Bench testing
    - Visual and dimensional inspection
    - Tensile Testing
    - Flexibility and Kink Resistance
    - Torque Verification
    - Leak/Vacuum Testing
    - Stent Interaction Testing
- Packaging testing
    - Visual Inspection
    - Pouch Bubble Leak
    - Pouch Seal Strength
- Biocompatibility testing- conducted in accordance with ISO 10993-1 including:
    - Cytotoxicity
    - Sensitization
    - Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Pyrogenicity (material mediated)
    - Hemocompatiblity- including hemolysis, complement activation, platelet and leukocyte and partial thromboplastin time
- Sterilization validation testing
- Corrosion testing

- Simulated use testing- in a tissue and thrombus model
- Animal testing, including chronic GLP animal studies which evaluated thrombogenicity

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. In addition, all user requirements were validated. Based on the similarities between the two devices, no clinical studies were deemed necessary to support this submission. All non-clinical test results demonstrated that the acceptance criteria were met and the device conforms to the product specifications.

Conclusions
Based upon the Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Recana Thrombectomy Catheter System has been shown to be substantially equivalent to the predicate device. The differences between the Recana Thrombectomy Catheter System and the predicate as well as the reference device do not raise new or different questions relative to safety or effectiveness.