April 13, 2023

InterVene, Inc.
% Mark Smutka
Regulatory Consultant
10984 Northseal Square
Cupertino, California 95014

Re: K222185
Trade/Device Name: Stratus Infusion Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: NPG
Dated: July 21, 2022
Received: July 22, 2022

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 (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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2023.04.13 10:04:56 -04'00'

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)*
K222185

Device Name
Stratus Infusion Catheter

Indications for Use *(Describe)*
In selective areas of peripheral veins between 7 and 16 mm in diameter, the Stratus Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents into the vein wall or perivascular area, or intraluminally.

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.

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Premarket Notification 510(k) Summary for the Stratus Infusion Catheter

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: K222185

Applicant Information:

Date Prepared:	July 21, 2022
Name:	InterVene, Inc.
Address:	415 Grand Avenue, Suite 302 South San Francisco, CA 94080
Contact Person:	Mark Smutka, Consultant msmutka@comcast.net
Mobile Number:	(408) 981-7531

Device Information:

Device Trade Name:	Stratus Infusion Catheter
Common Name:	Continuous Flush Catheter
Classification Name(s):	Continuous Flush Catheter
Product Code/ Regulation:	NPG / 21 CFR 870.1210
Classification:	Class II

Predicate Device:
Bullfrog Micro-Infusion Device - K161402

Subject Device Description
The Stratus™ Infusion Catheter is a peripheral infusion catheter designed to access an intraluminal, intramural, or perivascular vein wall layer and infuse fluid diagnostic and/or therapeutic agents. The Stratus Infusion Catheter is a non-implantable device that is provided sterile and is intended for single patient use.

The Stratus Infusion Catheter is designed to accommodate individual vein anatomies or disease progression (e.g., thrombosis), by the catheter platform allowing multiple infusions and infusion locations per device.

Subject Device Indications for Use
In selective areas of peripheral veins between 7 and 16 mm in diameter, the Stratus Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents into the vein wall or perivascular area, or intraluminally.

Predicate and Subject Device Comparison
The table below provides a comparison of the Stratus Infusion Catheter to the predicate device, the Bullfrog Micro-Infusion Device.

Comparison of Subject Device to Predicate Device:

Characteristic	Stratus	Bullfrog	Comparison
Name	Stratus Infusion Catheter	Bullfrog Micro-infusion Device	N/A
Regulation Number	21 CFR 870.1210	21 CFR 870.1210	Same
Regulatory Class	Class II	Class II	Same
Product Code	NPG	KRA	Equivalent
510(k) Number	N/A	K161402	N/A
Indications for Use	In selective areas of peripheral veins between 7 and 16 mm in diameter, the Stratus Infusion Catheter is intended for the infusion of diagnostic and therapeutic agents into the vein wall or perivascular area, or intraluminally.	In selective areas of peripheral and coronary vessels, the Bullfrog Micro-Infusion Device is intended for the infusion of diagnostic and therapeutic agents into the vessel wall and perivascular area, or intraluminally.	Indications for Stratus Infusion Catheter are a subset of the predicate device. The Stratus Infusion Catheter indications do not include coronary vessels or arteries. All other indications are unchanged. No impact on safety or effectiveness of the product.
Reusable	Single-Use and Disposable	Single-Use and Disposable	Same
Power Source	No power source or console required	No power source or console required	Same
Radiopaque	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	Same
Catheter Size	14 Fr	5 Fr	Catheter shaft diameters of the Bullfrog and Stratus differ to facilitate the capabilities of each. The Stratus was designed for the specific needs of large deep veins while the Bullfrog will also accommodate smaller vessels including arteries. The Stratus 14Fr size does not impact safety or effectiveness. Many other venous interventional 14F products are utilized in the same anatomy.
Vessel Size	7-16 mm	2-16mm (includes coronary vessels)	Indicated vein sizes are a subset of the predicate

			device. The Stratus Infusion Catheter indications do not include coronary vessels or arteries. No impact on safety or effectiveness of the product.
Needle Size	25.5 Ga	34 Ga	Stratus needle is slightly larger than the Bullfrog needle. Both devices utilize needles that are among the smallest of intravenous injection and infusion needles. There is no impact on the safety or effectiveness of the Stratus product.
Needle Penetration Depth	0.5mm to 1.5mm	1.5 mm	Maximum needle penetration depth is the same as the predicate. The needle height/penetration depth for the Stratus Infusion Catheter can be adjusted by the user across the entire range based on location and application as well as from one infusion to the next. No impact on safety or effectiveness of the product.
Needle Deployment Orientation	Parallel to catheter	Perpendicular to catheter	The Mercator Bullfrog has a needle that protrudes perpendicularly to the target location and engages the vessel as soon as the balloon is inflated to a specific diameter relative to the lumen. The Stratus Infusion catheter has a needle that runs parallel to the vessel and is advanced in a precise fashion by the user after the balloon has been fully inflated to the desired diameter. No needle engagement occurs until the user deliberately advances the needle. Engagement of the target infusion site is controlled by the user and does not

			introduce any new or increased risks (relative to the predicate) for engaging nearby vessels, arteries, or structures such as organs, bladder, etc. No impact on safety or effectiveness of the product.
Use of Guide Wire	.035”	.014”	An 0.035” Guidewire is the most common wire utilized in conjunction with venous interventions in this anatomy. No impact on safety or effectiveness of the product.
Balloon Material	SEBS 65A compliant balloon	Semi-rigid polymer actuator balloon	SEBS is a medical grade polymer utilized in other venous interventional devices. No impact on safety or effectiveness of the product.
Balloon Sizes	7-16 mm (compliant balloon, size based on inflation volume)	2-4mm, 3-6mm, 4-8mm and 6-16mm	Indicated balloon sizes are a subset of the predicate device balloons. The Stratus Infusion Catheter indications do not include coronary vessels or arteries. No impact on safety or effectiveness of the product.
Infusion Flow Rate	No more than 1 cc (mL) in 30 seconds	0.1-0.2mL per 5 seconds	Similar infusion flow rate. No impact on safety or effectiveness of the product.
Catheter Working Length	80 cm	145 cm	Shorter working length of Stratus Infusion Catheter is designed for intended access and treatment of selective areas of peripheral veins between 7 and 16mm in diameter. No impact on safety or effectiveness of the product.
Sterilization Method	E-beam Radiation	Radiation	Equivalent

Table 1 - Comparison between subject and predicate device

Testing Completed
The following design verification and validation testing was performed and successfully completed on the Stratus Infusion Catheter:

- Bench testing
- Packaging testing
- Biocompatibility testing – testing included cytotoxicity, sensitization, intracutaneous reactivity, acute system toxicity, pyrogenicity, complement activation, hemolysis (direct contact and extract method), partial thromboplastin time, platelet and leukocyte count and thromboresistance
- Sterilization validation testing
- Corrosion testing
- Luer testing
- Simulated use testing
- Human factors testing
- Animal testing, including a chronic GLP animal study

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. In addition, all user requirements were validated.

Summary
Based upon the Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the Stratus Infusion Catheter has been shown to be substantially equivalent to the cited predicate.