March 4, 2021

CareFusion 2200, Inc.
Jane Weber
Regulatory Affairs Sr. Manager
75 North Fairway Drive
Vernon Hills, Illinois 60061

Re: K210324
Trade/Device Name: V. Mueller Cosgrove Flex Clamps, Model Number-CV1033, CV1061, CV1133, CV1161, CV1186
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: DXC
Dated: February 2, 2021
Received: February 4, 2021

Dear Jane Weber:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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)*
K210324

Device Name
V. Mueller Cosgrove Flex Clamps

Indications for Use *(Describe)*
The V. Mueller Cosgrove™ Flex Clamps are indicated to be used to occlude a blood vessel temporarily. Used in pulmonary and gastrointestinal procedures and can be used to clamp over indwelling catheters. Also used in minimally invasive and standard open cardiovascular procedures for temporary occlusion of a blood vessel.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY – K210324

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc.
Address	75 North Fairway Drive Vernon Hills, IL 60061
Phone number	(847) 362-8094
Establishment Registration Number	1423507
Name of contact person	Jane Weber
Date prepared	March 4, 2021
DEVICE INFORMATION	
Trade or proprietary name	V. Mueller Cosgrove™ Flex Clamp
Common or usual name	Vascular Clamp
Classification name	Vascular Clamp
Classification panel	74 Cardiovascular
Regulation	Class II per 21CFR 870.4450, Product code DXC
Product Code(s)	CV1033, CV1061, CV1133, CV1161, CV1186
Legally marketed device(s) to which equivalence is claimed	Cosgrove Flex Clamp – K974769 Cosgrove Flex Clamp Quick-Bend™ - K991589
Reason for 510(k) submission	Design and labeling modifications
Device description	Each V. Mueller Cosgrove™ Flex Clamp device consists of a ring handle, flexible shaft and jaw. The design of the flexible shaft allows the end user to bend the shaft following clamping of the blood vessel providing the user a clear field of visualization to the surgical site. The proposed device and the predicate device have a similar design, the same materials and the same manufacturing and fabrication methods/processes. The main difference between the subject device and the predicate device is a change to the wire configuration of the cable. In addition, the cleaning and sterilization instructions in the instructions for use were updated in accordance with current guidance. These changes do not raise different questions of safety or effectiveness.
Intended use of the device	To be used to occlude a blood vessel temporarily

Indications for use	Used to occlude a blood vessel temporarily. Used in pulmonary and gastrointestinal procedures and can be used to clamp over indwelling catheters. Also used in minimally invasive and standard open cardiovascular procedures for temporary occlusion of a blood vessel.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**Predicate Devices**	**New Device**
Type of Device	Reusable	Reusable
How Supplied	Non-Sterile	Non-Sterile
Sterilization Modalities	Pre-vacuum Steam Gravity Steam Ethylene Oxide	Pre-vacuum Steam Ethylene Oxide
Insert Jaw Lengths	33mm, 61mm, 86mm	33mm, 61mm, 86mm
Materials	Stainless Steel	Stainless Steel

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary – Design Modification

Characteristic	**Standard / Test / FDA Guidance**	**Results Summary**
Instrument strength	Strength Tests, Life Cycle Test	PASS
Device must be reusable	Cleaning and Sterilization Tests	PASS
Device is able to be cleaned and sterilized	AAMI TIR12, AAMI TIR30, ANSI AAMI ST79, ISO 11138, ISO 17664, ISO 17665	PASS
Device materials are biocompatible	ISO 10993	PASS

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

N/A – No clinical tests were conducted for this submission.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the non-clinical tests demonstrate the V. Mueller Cosgrove™ Flex Clamps meet all performance requirements and are substantially equivalent to the predicate devices.