DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 16, 2014

Synovis Micro Companies Alliance Incorporated
A Subsidiary of Synovis Life Technology Incorporated
Mr. Troy Thome
Regulatory Affairs Specialist
2575 University Avenue West, Suite 180
Saint Paul, Minnesota 55114

Re: K142309
Trade/Device Name: GEM™ Flow COUPLER™ Device and System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: MVR, DPW
Dated: August 18, 2014
Received: August 19, 2014

Dear Mr. Thome:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142309

Device Name
GEM Flow COUPLER Device and System

Indications for Use *(Describe)*
The Flow COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of veins and arteries normally encountered in microsurgical and vascular reconstructive procedures. The Flow COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the Flow COUPLER Device is used in conjunction with the Flow COUPLER Monitor, the Flow COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as needed basis for up to 7 days. The Flow COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.

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.

2.0 510(K) SUMMARY

Submitted by

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Date Prepared

August 11, 2014

Device Trade Name

GEM™ Flow COUPLER™ Device and System

Common Name

- Microvascular Anastomotic Coupler
- Cardiovascular Blood Flowmeter

Classification Name

Microvascular Anastomotic Coupler
Regulation Number: 21CFR § 878.4300
Regulation Name: Implantable Clip
Regulatory Class: II
Product Code: MVR, DPW

Predicate Device(s)

GEM Flow COUPLER Device and System: K132727
GEM Flow COUPLER Device and System; K093310

Device Description

The Flow COUPLER System consists of a Flow COUPLER Device and a Flow COUPLER Monitor. The Flow COUPLER Device is a sterile, single-use implantable pair of rings molded out of high density polyethylene with stainless steel pins on each ring. The Flow COUPLER Device is designed to serve as a mechanical, sutureless device for connecting veins or arteries. A probe-holder feature is molded on one Flow COUPLER ring and serves as the press-fit point of attachment for a pre-attached 20 MHz Doppler probe. The Doppler probe connects to the Flow COUPLER Monitor unit, via the external lead.

The Flow COUPLER Monitor and Doppler probe is a pulsed Doppler ultrasound system designed for the detection of blood flow in vessels. An audible ultrasonic signal is produced when the Doppler probe detects blood flow.

The Flow COUPLER Device and System has been specifically designed for use in end-to-end anastomosis of blood vessels and the detection of blood flow at the anastomotic site. On an as needed basis, blood flow can be detected for up to 7 days. The Flow COUPLER rings are intended to be a permanent implant. The Flow COUPLER probe is not intended to be a permanent implant; the probe should be removed, by gentle traction on the external lead, 3 to 14 days post-operatively.

Statement of Intended use

The Flow COUPLER Device and System is intended to be used in the anastomosis of veins and arteries normally encountered in microvascular and vascular reconstructive procedures and in the detection of blood flow and confirmation of vessel patency following end-to-end anastomosis of vessels.

Technological Comparisons

The Flow Coupler Device and System is acting as its own predicate and is therefore substantially equivalent having the same technological characteristics including:

- Intended use
- Indications for use
- Device functionality
- Device method of operation
- Device finished specifications
- Doppler probe (wire material, wire diameter, and insulation material)Power supply requirements
- Device monitor
- Packaging
- Sterilization method
- Shelf life

The modified Flow Coupler device has the following differences as compared to the predicate device:

- Device size range
- Device dimensions
- Additional stainless steel pins (2)

Technology/Device Testing

A risk assessment of the size range extension in the form of a Design FMEA and Health Hazard Analysis has been conducted in accordance with EN ISO 14971: 2012.

Bench testing on the 3.5mm Flow COUPLER line extension was performed to validate that the functional specifications were not affected by the line extension. Testing included: shock and vibration, pin alignment (visual), ring retention, probe signal, ring separation, and probe to COUPLER separation force.

The risk assessment and bench testing of this device demonstrate that the device is substantially equivalent to the predicate device.

Summary

The device is substantially equivalent to the predicate device with respect to biocompatibility, manufacturing process, product performance, indications, sterilization, shelf life, packaging, and safety and efficacy.