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

ArthroCare Corporation
Ms. Laura N. Kasperowicz
Sr. Manager, Regulatory Affairs
15285 Alton Parkway, #200
Irvine, CA 92618

JUL 27 2015

Re: K070671
Trade/Device Name: Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCW
Dated (Date on orig SE ltr): March 9, 2007
Received (Date on orig SE ltr): March 12, 2007

Dear Ms. Kasperowicz,

This letter corrects our substantially equivalent letter of April 6, 2007.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K070671



# INDICATIONS FOR USE STATEMENT

510(k) Number: K 070671

Device Name: Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector

Indications for Use:

The Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector is indicated for use for placement of braided polyester and polyethylene suture through soft tissue in endoscopic and other limited access procedures.

| | | | | |
|---|---|---|---|---|
| Prescription Use (Part 21 CFR 801 Subpart D) | X | AND/OR | Over-The-Counter Use (21 CFR 801 Subpart C) | NO |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070671

K070671



1/2

# 510(K) SUMMARY

ARTHROCARE CORPORATION
OPUS SMARTSTITCH SUTURE DEVICE WITH PERFECTPASSER

APR - 6 2007

## General Information

| | |
|---|---|
| **Submitter Name/Address:** | ArthroCare Corporation<br>680 Vaqueros Avenue<br>Sunnyvale, CA 94085-3523 |
| **Establishment Registration No.:** | 2951580 |
| **Contact Person:** | Laura N. Kasperowicz<br>Sr. Manager, Regulatory Affairs |
| **Date Prepared:** | March 9, 2007 |

## Device Description

| | |
|---|---|
| **Trade Name:** | Opus® SmartStitch™ Suture Device |
| **Generic/Common Name:** | Endoscopic suture device |
| **Classification Name:** | Endoscope and accessories<br>(Class II per 21 CFR 876.1500) |
| **Product Code:** | KOG |

## Predicate Device

| | |
|---|---|
| Opus SmartStitch Suture Device | K062244 (Cleared 10/02/06) |

## Product Description

The Opus® SmartStitch™Suture Device with PerfectPasser is designed to allow the surgeon the option to place a simple stitch or a mattress stitch through soft tissue in endoscopic and other limited access procedures.

## Indications For Use

The Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector is indicated for use for placement of braided polyester or polyethylene suture through soft tissue in endoscopic and other limited access procedures.

# 510(K) SUMMARY

## Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The Opus® SmartStitch™ Suture Device with PerfectPasser Connector is substantially equivalent to the existing Opus® SmartStitch™ Suture Device with PerfectPasser Connector cleared by the Food & Drug Administration (K062244). The difference between the Opus® SmartStitch™ Suture Device and the predicate device does not raise any questions regarding the safety and effectiveness. Furthermore, the materials are well characterized. The device, as designed, is as safe and effective as the predicate device.

## Summary and Reason for 510(k) Notification

The purpose of this 510(k) is to notify the Food and Drug Administration of a modification to the previously cleared device. The modification incorporates the same principal of operation and fundamental technology as the previously cleared Opus SmartStitch Suture Device with PerfectPasser Connector. The primary difference includes the addition of a material.