K062100

# 510(K) SUMMARY
## (as required by 807.92(c))

DEC - 5 2006

**Submitter of 510(k):**

Arjo Wiggins Medical, Inc.
1301 Charleston Regional Parkway, Suite 500
Charleston, SC 29492
Phone:

**Contact Person:** Dave Darby

**Date of Summary:** July 7, 2006

**Trade/Proprietary Name:** ArjoWrap 47/100 and 47/88

**Classification Name:** Wrap, Sterilization

**Product Code:** FRG

**Device Description:**

ArjoWrap is a sterilization wrap to be used by healthcare facilities to wrap other medical devices for terminal sterilization by steam or ethylene oxide. The ArjoWrap product is composed of two materials and will be offered two different weights. Each weight will be marketed in twelve sizes.

**Predicate Device:** K931202 – Sterisheet Sterilization Wrap, Arjo Wiggins

**Substantial Equivalence:**

Arjo Wiggins claims the proposed device to be substantially equivalent to the device previously cleared by FDA in K931202. The modifications to the predicate have been described in Section 5 of this submission. Arjo Wiggins claims this equivalence be cause the proposed device has an equivalent intended use, manufacturing materials, operating principles, and physical, operational and biological specification as compared to the predicate device.

The similarities and differences between the proposed and predicate devices have been identified and explained in the Comparison Matrix which has been included as Enclosure A of this Summary. These differences have no effect on safety and effectiveness.

**Intended Use:**

ArjoWrap is a single use, non-sterile sterilization wrap intended to be used by healthcare facilities to wrap other medical devices for terminal sterilization by steam or ethylene oxide. ArjoWrap maintains the sterility of the enclosed devices until they are used. ArjoWrap is not recommended for any type of irradiation sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 5 2006

ARJO Wiggins Medical, Incorporated
C/O Mr. Arthur Ward
Consultant
RMS Regulatory & Marketing Services, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K062100
Trade/Device Name: ArjoWrap 47/100 and 47/88
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 17, 2006
Received: November 21, 2006

Dear Mr. Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062100

Device Name: ArjoWrap 47/100 and 47/88

Indications for Use:

ArjoWrap 47/100 and ArjoWrap 47/88 models are single use, non-sterile sterilization wraps intended to be used by healthcare facilities to wrap other medical devices for terminal sterilization by steam or ethylene oxide. ArjoWrap 47/100 and ArjoWrap 47/88 maintain the sterility of the enclosed devices until they are used.

ArjoWrap 47/100 and ArjoWrap 47/88 are not recommended for any type of irradiation sterilization.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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