K070163

SECTION 5: 510(k) SUMMARY

Baxa

AUG - 3 2007

Submitted by:	Baxa Corporation
Contact Person:	Kimberly Zizik
Phone:	(303) 617-2242
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Date Prepared:	
Manufacturing Facility:	Baxa Corporation 14445 Grasslands Drive Englewood, CO 80112 Establishment registration number 1419106
Submitted Device:	PadLock™ Swabbable Cap Common Name: Set, Intravascular Administration (ODI)
Product Code:	ODI
Device Classification:	Class II Classification: 21 CFR § 880.5440 Intravascular administration set (a) *Identification.* An intravascular administration set is a device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, a flow regulator, a drip chamber, an infusion line filter, an I.V. set stopcock, fluid delivery tubing, connectors between parts of the set, a side tube with a cap to serve as an injection site, and a hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container. (b) *Classification.* Class II (performance standards)
Predicate Device:	Trade Name: Dual Luer Lock Cap Common Name: Set, Intravascula Administration Classification Name: [880.5440] Intravascular Administration Set (Class II) (FPA) Manufacturer: Baxter Healthcare Corporation 510(k) Number: K981318
Product Description:	Provides temporary aseptic closure of the male luer connector of the IV tubing while disconnected from the patient, replacing the need for disposable caps to maintain aseptic procedure.
Intended Use:	The PadLock Swabbable Cap provides temporary aseptic closure of the male luer connector of the IV tubing while disconnected from the patient, replacing the need for disposable caps to maintain aseptic procedure. The device is permanently attached to IV tube sets for general hospital use and is used repeatedly for the life of the administration set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Ms. Kimberly Zizik
Regulatory Assurance Supervisor
Baxa, Corporation
14445 Grasslands Drive
Englewood, Colorado 80112

Re: K070163
Trade/Device Name: Swabbable Cap
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: ODI
Dated: July 20, 2007
Received: July 23, 2007

Dear Ms. Zizik:

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

SECTION 4: INDICATIONS FOR USE

510(k) Number: K070163

Device Name: Swabbable Cap

Indications for use:

The Swabbable Cap provides temporary aseptic closure of the male luer connector of the IV tubing while disconnected from the patient, replacing the need for disposable caps to maintain aseptic procedure. The device is designed to be permanently attached to an IV administration set and used over the life of the administration set.

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

(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 Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K070163