K103165

5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Acacia, Inc. 785 Challenger Street Brea, CA 92821 (714) 257-0470 Contact: Fergie Ferguson
DATE PREPARED:	September 13, 2010
TRADE NAME:	Blood Sampling Set
COMMON NAME:	IV Extension Set
CLASSIFICATION NAME:	Intravascular Administration Set
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	FPA
PREDICATE DEVICES:	Elcam Medical Closed Swabable Stopcock and Minimal Residual Volume Luer Activated Swabable Stopcock (K060231) Acacia IV Extension Set (K895367)

NOV 10 2010

Substantially Equivalent To:
The Acacia, Inc. Blood Sampling Set is substantially equivalent in intended use, principal of operation and technological characteristics to the Elcam Medical Closed Swabable Stopcock and Minimal Residual Volume Luer Activated Swabable Stopcock (K060231) and Acacia IV Extension Set (K895367).

Description of the Device Subject to Premarket Notification:
The Blood Sampling Set consists of non-DEHP PVC tubing, and configured with one or more stopcocks with needleless valves, and a male luer lock for connection with the patients catheter. An optional configuration includes check valves, non-DEHP PVC tubing and transfer spike to allow for withdrawing flush solution from an IV bag into a syringe. All sets can be ordered with a choice of various on/off clamps, depending on the clinician's and hospital protocol.

The Blood Sampling Set will be provided as a sterile, single use, non-pyrogenic, disposable device and will be available in a variety of lengths and sizes.

Indications for Use:
The Blood Sampling Set is indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

Technical Characteristics:

The Blood Sampling Set has the same physical and technical characteristics to the predicate devices, since the proposed device integrates both of the predicate devices.

Biological Evaluation:

The materials used to manufacture the blood sampling set were originally evaluated and tested per ISO 10993 for the predicate Acacia IV Extension Set. None of the materials, manufacturing process, or sterilization process has changed since the testing was performed, therefore biocompatibility testing was leveraged from the previous 510(k) K895367. The following is a

summary of testing performed on all of the materials used in the manufacture of the Acacia, Inc. predicate device:

Cyctotoxicity
Sensitization
Irritation/Intracutaneous Toxicity
Systemic Toxicity
Sub-chronic Toxicity
Hemocompatibility
Pyrogenicity

None of the materials, manufacturing process, or sterilization process has changed from the approval of the predicate Elcam device for distribution, therefore biocompatibility testing was leveraged from the previous 510(k) K060231.

Performance Data:

All necessary verification and validation testing has been performed for the Blood Sampling Set to assure substantial equivalence to the predicate devices.

The following tests were performed and met the acceptance criteria as outlined in ISO 8536-4:

Bond Joint Strength
Fluid Flow
Leak Testing
Flow Rate Comparison (between proposed and predicate device)

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Blood Sampling Set is determined by Acacia, Inc., to be substantially equivalent to the existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

ACACIA, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

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Re: K103165
Trade/Device Name: Acacia Blood Sampling Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 26, 2010
Received: October 27, 2010

Dear Mr. Job:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
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): K103165

Device Name: Acacia Blood Sampling Set

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Indications for Use:

The Blood Sampling Set is indicated for fluid flow directional control and for providing access port(s) for administration of solutions. Typical uses include pressure monitoring, intravenous fluid administration and transfusion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 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)
vision of Anesthesiology, General Hospital
rection Control, Dental Devices

10(k) Number: K103165