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

DEC 23 2008

Regulatory Correspondent

AJW Technology Consultants Inc
962 Allegro Lane
Apollo Beach, FL 33572
awconsltng@aol.com

Submitter of 510(k):

Marcal Medical, Inc.
1114 Benfield Blvd, Suite H
Millersville, MD 21108
USA

Phone: (410) 987-4001
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Contact Person: Candace Keaton

Date of Summary: 6/17/08

Trade/Proprietary Name: Subcutaneous Needle Infusion Set

Classification Name: Set Administrative Intravascular

Product Code: FPA

Intended Use:
The Subcutaneous Infusion Set is designed specifically for the delivery of medication to the subcutaneous tissue

Device Description:
The subcutaneous needle infusion set consists of a sterile packaged kit including the infusion set and an adhesive dressing to hold the device in place. The unique Single, Bifurcated, Trifurcated, and Quadfurcated for the Sub-Q have a luer lock at one end and a 90 degree needle mounted to a butterfly stabilizer at the other end. The sets are convenient to use, associated with less trauma, and offer an opportunity to improve compliance cost-effectively through the use of a dedicated infusion set. The device is for single use only.

Predicate Device:
K020530 – Evans Medical, Inc – Evans Sub-Q, Model MC4206
K891072 – Multi-Med, Inc – Intravascular Administration Set.

Substantial Equivelance:
The Marcal Medical Subcutaneous Needle Infusion Set meets all established acceptance criteria for performance testing and design verification testing. The components of the Sub-Q Set are substantially equivalent to the predicate device presented in this 510k.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2008

Marcal Medical, Incorporated
C/O Mr. Arthur Ward
President
AJW Technology Consultants Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K082818
Trade/Device Name: Subcutaneous Needle Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 17, 2008
Received: September 30, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K082818

Indications for Use

510(k) Number (if known): _____

Device Name: Subcutaneous Needle Infusion Set

Indications for Use:

The Subcutaneous Infusion Set is designed specifically for the delivery of medication to the subcutaneous tissue

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson

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

510(k) Number: K082818