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AUG 15 2008

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Topic: **510(k) Summary as required by 21 CFR Section 807.92(c): Q-Core AP 34 multi-therapy Infusion Pump (External)**

To: Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville MD, 20850

Attn.: Document Control Clerk

Sec. 807.92(a)(1)

Contact person: Asher Kassel,
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Date of Summary: 31 Dec., 2007

Sec. 807.92(a)(2)

Trade/Proprietary Name AP 34 multi-therapy Infusion Pump

Common/Usual Name Ambulatory Infusion Pump
Intravascular Administration Set

Classification Name *Pump, Infusion,
*Intravascular Administration Set
*Accessories, Pump, Infusion

Classification **Class II:**
21 CFR 880.5725 for infusion pump
21 CFR 880.5440 for IV Administration Set

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Product Codes	FRN – Infusion Pump FPA – IV Administration Set MRZ – Accessories for Infusion Pump
Part Number of AP 34	05022-100-0001-PMP
Part Numbers of AP 34 Sets	05060-520-000X-ASMM-0X

Sec. 807.92(a)(3)

Predicate Devices

*CADD-Prizm Model 6100 (K960826)
*Bodyguard Infusion System and infusion sets (Caesarea Medical Electronics - K031749)
*IV Administration Sets with Ultrablock UV-resistant tubing (B. Braun Inc. – K041490).

Sec. 807.92(a)(4):

Device Description:
The Q-CORE AP 34 multi-therapy Infusion Pump is a software driven, volumetric, ambulatory infusion pump for the delivery of measured amounts of medication or parenteral nutrition at a controlled rate. The AP 34 uses Q-Core approved disposable Administration Sets, including the Q-Core designed Magic Straw™ cassette.
The AP 34 operates by means of an electro-mechanical pumping mechanism based on Q-Core patented **Electromagnetic Flow Control** (EFC™) valve technology.
The pumping mechanism is a single channel, with an integral pressure sensor and real time flow correction capacity; the pumping mechanism produces a peristaltic pumping action.

Top assembly of the AP 34 infusion pump:
The AP 34 consists of three main assembly parts:

i. pumping module
ii. modular touch screen unit
iii. Optional Q-Core designed cradle for holding and charging the pump when the pump is not in ambulatory use.

Major components of the AP 34 infusion pumps:
The major components of the AP 34 infusion system are as follows:

i. Electronic circuitry
ii. Mechanical system for liquid delivery
iii. Power supply and battery charger
iv. Magic Straw™ disposable cassette
v. Q-Core approved Administration Sets for home and hospital use
vi. Optional Q-Core designed cradle

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Power supply:
The device is powered by either a Li-on rechargeable battery pack or via a medical grade AC/DC power supply. The pump connects to an AC line via an external AC/DC power adaptor, or via the pump's cradle which has an internal AC/DC power adapter. The cradle is mounted an IV pole. In the event of AC power loss, or when moving patients, the pump operates on an internal rechargeable battery.

The battery is always in a state of charging during AC power use. The battery is recharged by a wall mounted charger that plugs into a standard (100-240 AC) alternating current wall socket. A "fuel gauge" type indicator on the pump's LCD display continuously shows the status of the battery capacity. A blinking LED (yellow) on the front panel of the infusion pump indicates that the battery is in a state of charging; LED OFF indicates that the battery is fully charged. When the pump is in operation, a green LED lights up; when there is no power input to the pump, the green LED is OFF.

Ambulatory use of the AP 34 infusion pump:
A waist-pack is available for use under ambulatory conditions. The modular design allows the patient to operate the pump without having to disconnect the pump from its set or remove it (the pump) from the pouch. The pump may be operated horizontally or vertically.

Administration Set (AS).
Different configurations of disposable Administration Sets are available depending on the required use of the AS, e.g. for hospital or home use; or for PCA or TPN. Depending on the desired configuration, the Administration sets may include a male luer, PVC tubing, a Y-injection valve and an infusion filter. All Sets include the Q-Core "Magic Straw"™ cassette with silicone tubing and the anti-free flow valve (AFVV). The Magic Straw has integrated safety features including anti-free flow protection during system failure and anti-free flow protection during set loading/unloading. The Q-Core approved Administration Sets for the AP 34 are supplied sterile and are intended for single-patient use only. All AP 34 Administration Sets for sale in the USA are non-DEHP, latex free, and non-pyrogenic.

Sec. 807.92(a)(5)

Intended use of the AP 34 multi-therapy infusion pump and Sets:

The intended use of the AP 34 device is to administer controlled doses of medication and parenteral nutrition feeding solutions to adult and pediatric patients in hospital, long-term care facilities or home care settings.

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Sec. 807.92(a)(6)

Summary of the technological characteristics of the AP 34 infusion system in comparison to the predicate devices:

AP 34 infusion pump:

Similarities:
The proposed AP 34 multi-therapy Infusion Pump is similar to the predicate devices in the following respects:

1. All the pumps are volumetric and SW controlled, with variable flow rates and pumping action
2. All the pumps have the same intended use – delivery of programmed doses of mediation or nutrition at selected rates – and can be used in the hospital and home environments
3. All the pumps have similar programming options and the same delivery modes – PCA; TPN; CONTINUOUS and INTERMITTENT.
4. All the pumps have similar safety features in order to prevent free flow; and similar alarms, such as detection of upstream and downstream occlusion; low battery; empty set; dose done and pump mechanism failure
5. All the pumps may be operated in any orientation, and come with an optional waist pack (pouch) for ambulatory use.

Differences:

i. The Q-Core AP 34 infusion pump has a modular touch screen
ii. The pumping mechanism of the AP 34 is based on electromagnetic flow control (EFC) technology.

Administration Sets for the AP 34 pump:

Similarities:
The proposed AP 34 Administration Sets are similar to the infusion sets of the predicate device (K031749) in the following respects:

1. Both the Sets of Q-Core and the predicate device Sets (henceforth "Both Sets") have the same or similar technological characteristics
2. Both Sets are used for intravenous infusion with the respective infusion pumps
3. Both Sets can be used only by or under the order of a licensed medical
4. practitioner
5. Both Sets are latex-free, and consist of standard, conventional components such as Luer locks, PVC tubing, Y-Connector, clamp for tubing
6. Both Sets have similar means to protect against free flow
7. Both Sets have components made from the same or similar material
8. Both Sets use materials with the same characteristics (non-toxic, non-DEHP, latex free)
9. Both Sets are provided in sterile packaging, by way of EO
10. Both Sets are intended for single use
11. Both Sets are recommended for use of up to 24 hours only
12. Both Sets are intended for hospital and home use.

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Differences:
The major differences between the Administration Sets for the AP 34 multi-therapy infusion pump and the Sets for the predicate device are the following:

i. The AP 34 uses a proprietary "Magic Straw" cassette with the Q-Core designed
Anti Free Flow Valve and silicone tubing.
ii. The exact configuration of the Administration Sets for the AP 34 may differ from those of the predicate device according to customer specifications and to the operational characteristics of the AP 34.

Light-safe Administration Sets for the AP 34 pump:

Similarities:
The proposed light-safe AP 34 Administration Sets are similar to the light-safe infusion sets of the predicate device (K041490) in the following respects:

1. Both the Sets of Q-Core and the predicate device Sets (henceforth "Both Sets") have the same or similar technological characteristics
2. Both Sets have the same intended use, namely intravenous infusion of IV fluids involving light sensitive solutions
3. Both Sets can be used only by or under the order of a licensed medical
4. practitioner
5. Both Sets are latex-free, and consist of standard, conventional components such as male luer lock, tubing, clamp, tubing, etc.
6. Both Sets use materials with the same characteristics (non-toxic, non-DEHP, latex free)
7. Both Sets are intended for single use
8. Both Sets are provided sterile and non-pyrogenic

Differences:
The major differences between the light-safe Administration Sets for the AP 34 multi-therapy infusion pump and the light-safe Sets for the predicate device are the following:

i. The AP 34 uses a proprietary "Magic Straw" cassette with the Q-Core designed
Anti Free Flow Valve and silicone tubing.
ii. The exact configuration of the Administration Sets for the AP 34 may differ from those of the predicate device according to customer specifications and to the operational characteristics of the AP 34.

Conclusion of SE comparison:
We submit that the Q-Core AP 34 multi-therapy Infusion Pump and its dedicated Administration Sets are substantially equivalent to the predicate devices and that the technological characteristics of the AP 34 infusion pump and its Sets do not raise any new issues of safety and effectiveness. The substantial equivalence claim is supported by the information provided in this 510(k) submittal.

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Sec. 807.92(b)(1)

Non-clinical performance data for the AP 34 pump:
The AP 34 has been subject to extensive bench testing in order to ensure that the device meets the applicable safety, performance and accuracy requirements set out in the IEC 60601-2-24 standard for infusion pumps. IEC 60601-2-24 contains specific test procedures and test methodologies used to measure the accuracy of delivery and functional performance of infusion pumps at different flow rates, over various intervals of time.

The AP 34 was tested for an independent testing laboratory for compliance with the following standards:

1. **Electrical safety**: IEC 60601-1
2. **EMC**: IEC 60601-1-2
3. **Particular requirements for infusion pumps**: IEC 60601-2-24

Non-clinical performance data for the AP 34 Administration Sets:
The AP 34 Administration Sets have been subject to extensive bench testing according to the guidelines set out in the ISO 8536-4 and ISO 8536-8 standards for infusion sets.

Biocompatibility Testing
All materials used in components that are in indirect contact with the patient's body were tested for biocompatibility and are in compliance with the ISO 10993-1 standard on biocompatibility.

Sec. 807.92(b)(2)

Clinical Testing
Clinical studies were not deemed necessary regarding the use and performance of the AP 34 multi-therapy Infusion Pump and the Administration Sets.

Potential adverse effects
The potential adverse effects that may arise when using the AP 34 multi-therapy Infusion Pump, as well as other non-implantable ambulatory infusion pumps cleared for marketing by the FDA, include the possibility of under-infusion, over-infusion, or no infusion.
Potential adverse effects of using Administration Sets include rupture, leakage and air bubbles in the tubing.

Sec. 807.92(b)(3)

Conclusion of testing of performance and accuracy data: AP 34 pump
The conclusions drawn results of nonclinical tests (electrical safety, EMC, performance and accuracy), indicate that the AP 34 infusion pump is as safe, as effective, and performs as well or better than the legally marketed predicate devices identified in Sec. 807.92(a) (3) above.

Conclusion of testing of performance and accuracy data: AP 34 Administration Sets
The conclusions drawn results of nonclinical tests (safety, performance and accuracy), indicate that the Administration Sets for AP 34 infusion pump are as safe, as effective, and perform as well or better than the legally marketed predicate device identified in Sec. 807.92(a) (3) above.

REFERENCES

1. **IEC 60601-1:**
   General Requirements for Safety for Medical Electrical Systems - part 1, (**1988**);
   Amendment 1 – **1991**-11;
   Amendment 2 – **1995**-03

2. **IEC 60601-1-2 (2001)**:
   General Requirements for Safety
   Collateral Standard: Electromagnetic compatibility - Requirements and tests.

3. **IEC 60601-2-24 (1998):**
   Medical Electrical Equipment: Particular requirements for the safety of infusion pumps and controllers

4. **ISO 8536-4 (2004):**
   Infusion equipment for medical use — Part 4:
   Infusion equipment for single use, gravity feed

5. **ISO 8536-8 (2004):**
   Infusion equipment for medical use — Part 8:
   Infusion equipment for use with pressure infusion apparatus

6. **ISO 10993-1 (2003):**
   Biological evaluation of medical devices, Part 1: Evaluation and Testing

7. **FDA Guidance Document** (updated on 5 Sept., 1997):
   Guidance on the Content of Premarket Notification [510(k)] Submissions for External Infusion Pumps

8. **FDA Guidance Document** (15 April, 2005):
   Guidance for Industry and FDA Review Staff - Intravascular Administration Sets Premarket Notification Submissions [510(k)]

9. **Infusion Pump Survey Report** published by The Canadian Institute for Safe Medication Practices, Y2004–06–08

10. **Medical Devices Agency** (UK) Report on Infusion Systems, Reference no. MDA DB2003 (02), March 2003.

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Signature:

A Kassel

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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AUG 15 2008

Q-Corc Limited
C/O Mr. J.A. van Vugt
Responsible Third Party Official
KEMA Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K082182
Trade/Device Name: AP 34 Multi-Therapy Infusion Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, MRZ, FPA
Dated: July 23, 2008
Received: August 1, 2008

Dear Mr. van Vugt:

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.

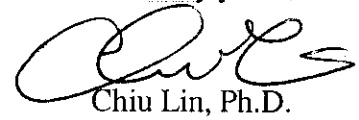
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 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

K082182

Indications for Use

510(k) Number (if known):

Device Name: AP 34 multi-therapy Infusion Pump System

- **Indications For Use:**

The AP 34 is a multi-therapy infusion pump system designed for the volumetric infusion of medication and nutritional fluids to patients in the hospital, homecare and outpatient environments in the following delivery modes: CONTINUOUS; INTERMITTENT; PCA (Patient Control Analgesia) and TPN (Total Parenteral Nutrition). The AP 34 is not intended for the following use or substances:

- Delivery of blood or cellular blood products
- Intra-cardiac use.

The AP 34 infusion pump includes the following accessories:

- Bolus cable
- Q--Core approved AC/DC adaptor (external)]
- Cradle (optional) and power cable for cradle
- Rechargeable battery pack for pump
- PCA cover box
- Communication cables

The dedicated Q-Core Administration Sets for the AP 34 infusion pump are intended for single-patient use only.

The AP 34 infusion pump system is for prescription use only.

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

(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: K082182