DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

Mr. Gali Tzury
Quality Assurance Manager
Caesarea Medical Electronics, Limited
Caesarea Industrial Park
16 Shacham Street
P.O. Box 4294
Caesarea,
ISRAEL 38900

Re: K060479
Trade/Device Name: *BodyGuard* Infusion Pump System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, DQA
Dated: February 13, 2006
Received: February 23, 2006

Dear Mr. Tzury:

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,

Amy Quilon for

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:

Device Name: *BodyGuard* Infusion Pump System

Indications for Use:
The *BodyGuard* infusion Pump system is designed for infusion and monitoring. The pump is intended for infusion of medications or fluids requiring continuous or intermittent delivery at precisely-controlled infusion rates through clinically acceptable routes of administration, including intravenous, subcutaneous, percutaneous, intra-arterial, epidural, enteral, in close proximity to nerves, and into an intraoperative site (soft tissue/body cavity/surgical wound site). Monitoring accessory currently includes Pulse Oximeter, used for non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The system is intended for patients who require maintenance medications, analgesics, PCA therapy, parenteral and enteral nutrition fluids, chemotherapeutic agents and general fluids therapy. The system is indicated for use with adult, pediatric and neonatal patients in hospital and home care environments.

The *BodyGuard* Infusion system includes:
Infusion Pump (one/dual channel models)
Docking Station
Bolus cable (optional)
Drop sensor (optional)
Pulse Oximeter (optional)

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)

(Div)
of Anesthesiology, General Hospital,
Infection Control, Dental Devices

Number: K060479