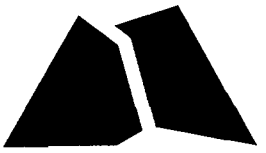

McKinley

SEP 2 3 2003

McKinley Medical LLLP
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K032642

510(k) Summary—Special 510(k) for Modifications to the McKinley Beeline System

Date Prepared:	15 August 2003
Submitter:	McKinley Medical, LLLP 4080 Youngfield Street Wheat Ridge, CO 80033 Phone: 303-420-9569 Fax: 303-420-8585 Contact for questions: Andy Lamborne
Trade Name:	Beeline Motiv
Common Name:	Spring Pump & Kit
Classification Name:	Infusion Pump
Classification Panel:	General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Panel:	80
Procode:	FRN – Infusion Pump
Original cleared 510(k):	K990461
Establishment Registration:	1723533
Owner/Operator Number:	9027257

5. Summary of Safety and Effectiveness of the Beeline System

5.1 This submission is intended to notify the Food and Drug Administration that McKinley Medical, LLLP intends to market a modification to an existing device (K990461) called the Beeline system. Modifications to the existing device are extension of the flow rate range, addition of a larger reservoir volume, and addition of procedure kits.

5.2 The original cleared device demonstrating substantial equivalence is the McKinley Spring Pump Disposable Infusion Pump (K990461).

5.3 A supporting predicate device also demonstrating substantial equivalence is McKinley's Accufuser, Accufuser Plus & standard procedure kit (K023098).

5.4 The cleared indications for use for the Beeline system are as follows:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

5.5 Summary Description of the Beeline system

5.5.1 The Beeline device consists of a spring-pressurized, syringe-like medication reservoir with a flowrate-controlling administration set. Medication is held between the barrel and piston of the infuser. A spring applies force against the piston, pressurizing the medication. The administration set includes a flow restrictor component with controlled internal diameter and length. The flow rate at which medication is dispensed from the system is a function of the pressure applied to the medication and the dimensions of the flow restrictor component.

5.5.2 The size of the reservoir and the amount of flow restriction are varied during manufacturing to yield a variety of product codes with differing infusion volumes and flowrates.

5.5.3 A procedure kit provides various components that facilitate setup and use of the Beeline system. Examples of kit components include items such as a prep tray, sterile drape, transfer syringe, medication/chart labels, catheter & introducer, dressing, tape, gauze, prep pads/wipes, carrying case, etc. Multiple kit product codes are made, with the contents varied as applicable for the particular procedure.

5.5.4 The Beeline system is intended for single patient use.

5.5.5 Device Specifications

a. The Beeline system has fill volumes and flow rates substantially equivalent to the named predicate devices.
   - The nominal fill volume of the system is 100 mL (small infuser) or 275 mL (large infuser).
   - The nominal flow rate ranges from 0.4 to 10 mL/hr.
   - Flow rate accuracy is ±15% of nominal flow rate, for all product codes.
   - Residual volume is 5 mL or less.

b. Operating pressure averages approximately 6 psi.

c. As with the identified predicate devices, fluid viscosity, temperature, and head height affect flow rate.

- The device is calibrated to deliver at the nominal flow rate using D5W (5% dextrose in water) as the infusate. Changing from D5W to sterile water increases flow rate by approximately 10%.
- The device is calibrated to deliver at the nominal flow rate at skin temperature (86 °F). Flow rate changes by approximately 1% per °F.
- The device is calibrated to deliver at the nominal flow rate with the medication reservoir 18" below the infusion site. Raising the infuser will increase the flow rate by less than 1% per inch.

d. The fluid path materials are chosen from those commonly used in infusion devices.
   - Examples of the types of material used include polypropylene; polyethylene; PVC; acrylic; polycarbonate; ABS; silicone, butyl, nitrile, or other latex-free rubber; polyimide; nylon; PTFE; cellulose acetate; glass; stainless steel. The actual materials used vary slightly, depending on the product code (e.g., different procedure kit components may use different materials).
   - The Beeline system and the identified predicate devices control the flow rate with a length of micro-bore tubing made from glass, PVC, polyethylene or similar appropriate material.
   - All fluid path materials of the Beeline system are in conformance with ISO 10993-1 biocompatibility standards.

e. There are currently no approved performance standards established for spring pumps under Section 514 of the Food, Drug and Cosmetic Act.

f. Packaging is suitable for both EtO and gamma radiation sterilization.
   - For product codes sterilized with EtO, the EtO cycle is validated per ISO 11135 and residuals are validated per ISO 10993-7.
   - For product codes sterilized with gamma radiation, the sterilization dose is validated per ISO 11137.

5.5.6 Device Safety Functions

a. The Beeline system provides a fixed flow determined by the applied force from the compressed spring and the flow restriction induced by the dimensions of the flow restrictor. The Beeline system is not subject to infusion runaway conditions as may occur with some electronic pumps.

b. The administration set includes a clamp, allowing the user to stop flow if necessary.
c. The administration set has a 1.2-micron or smaller air-eliminating filter.
d. The fluid path is clear or translucent, allowing visual inspection of the contents.
e. The medication reservoir has syringe-like graduation marks to provide an approximate indication of remaining volume, allowing the user to monitor the infusion progress.

5.6 Conclusion: The modified Beeline system does not raise any new safety and efficacy concerns when compared to the original device that is already legally marketed. The Beeline system is substantially equivalent to the named predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2003

Mr. Andrew N. Lamborne
Director of Engineering
McKinley Medical, LLLP
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K032642
Trade/Device Name: Beeline Motiv Spring Pump & Kit
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: August 15, 2003
Received: August 27, 2003

Dear Mr. Lamborne:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use Statement

Applicant: McKinley Medical, LLLP

510(k) Number (if known): K032642

Device Name: Beeline System

Indications for Use:

The Beeline system is indicated for intravenous, intra-arterial, enteral, subcutaneous and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

The Beeline system is also intended to provide continuous infusion of a local anesthetic directly into the intraoperative site for postoperative pain management.

(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: K032642

(Optional Format 3-10-98)