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SECTION E – 510(k) Summary for the Sgarlato PainFree pump

General

The Sgarlato PainFree pump is mechanically the same device currently legally marketed by Sgarlato Labs for continuous infusion of liquid medication into an intraoperative site for postoperative pain management. Similar mechanically-driven, infusion pumps with the same flow and reservoir capacity include percutaneous, subcutaneous, intramuscular and epidural infusion sites as alternative routes for administration of medication. Because the Sgarlato PainFree pump offers equivalent flow rates, similar reservoir volumes, and similar materials in its construction, Sgarlato laboratories believes that its use with alternative administration routes should be considered substantially equivalent to currently cleared predicate devices. Predicate Devices cited are the Paragon Infusion Kit K984146 and the Sgarlato Pain Control Infusion Pump K990101.

Similarities

This infusion pump is one of a multiplicity of similar general purpose devices marketed to provide continuous infusion of moderate amounts of liquid medication (100-200 ml) over an extended period of time without use of electrical power. These mechanically-driven, single-use or reusable infusion pumps are therefore suitable for ambulatory use and can provide medication infusion via catheters for extended periods ranging from a few hours to several days.

The Predicate Devices, the I-Flow Paragon Infusion Kit (K984146) and the Sgarlato Pain Control Infusion Pump (K990101) offer similar flow rates and reservoir capacities. They both are mechanical devices that use spring energy to provide pressurized medication. They use micro-bore flow restrictors to meter the flow from a pressure vessel to the desired rate desired at the infusion site. They both include epidural-style medication catheters for delivery of medication to the site and offer the ability to easily exchange flow restrictors in a given setting. They offer y adapters to split the reservoir volume to multiple sites in a given surgical setting. They provide convenience kits with a filling syringe, needle introducer for the catheter, and various accessories to affix the catheter to the patient, label and carry the pump, etc. Neither device is intended for use in delivering blood, blood product, lipids, or for other intravenous or TPN use.

Differences

The primary difference between the original Sgarlato Pain Control Infusion Pump K990101) and the Sgarlato PainFree pump is expansion of the sites indicated for infusion. The original device listed percutaneous infusion via a catheter to an intraoperative site. The extended indication adds subcutaneous, and epidural sites.

The PainFree pump is intended to infuse liquid medications such as corticosteroids or other anti-inflammatory compounds of the same approximate density of local anesthetics. Compounds such as blood or lipids that may clog the medication filter included in the set are not intended to be used. The original Sgarlato Pain Control Infusion pump was primarily used for infusing local anesthetics.

The primary difference between the I-Flow pump and the PainFree pump is the method of pressurizing the reservoir. The I-Flow device uses a spring/scissors mechanism to apply pressure to a pliable drug bag within a hard shell. The PainFree pump uses a syringe-like reservoir that compresses the plunger against a self-contained spring to apply pressure to the liquid volume in the syringe. The Sgarlato device is distributed as a single-use sterile device. The I-Flow device may be reused and/or sterilized by the user.

Conclusion

The PainFree pump is substantially equivalent mechanically to its predecessor Pain Control Infusion Pump from Sgarlato. The PainFree pump is substantially equivalent in terms of identified infusion sites to the I-Flow Paragon device. See Table 1 for more specific information.

Comparison to legally marketed Devices

Item	Paragon Infusion Kit (K984146)	Sgarlato PCIP (K896422)	Sgarlato PainFree Pump (review item)
Intended Use	Continuous infusion of medication into an intraoperative site for general surgery and pain management. The pump itself is for general infusion use.	Continuous infusion of local anesthetic into a surgical site for postoperative pain management	Continuous infusion of medication into a target site for pain management
Routes of Administration	Percutaneous, subcutaneous, intramuscular, and epidural	Percutaneous	Percutaneous, subcutaneous, and epidural
Contraindications	Not for intravenous delivery. Not intended for blood, blood products, lipids, or fat emulsions	Not for epidural, subcutaneous, or vascular drug delivery. Not for delivery of blood, blood products, or TPN	Not for intravenous delivery. Not intended for blood, blood products, lipids, or fat emulsions
Reuse	Re-usable pump, single use administration sets	Single Use	Single Use
Fill Volumes	100 ml	100 or 200 ml	100 or 200 ml
Flow Rates	0.5,1,2,4, or 10 ml/hr	0.5,1,or 2 ml/hr	1,2, or 4 ml/hr
Flow control	Micro-bore tubing with medication filter	Micro-bore tubing with 5 micron medication filter	Micro-bore tubing with 5 micron medication filter
Pump Mechanism	Spring-scissors plate compressing PVC bag	Spring-powered syringe plunger	Spring-powered syringe plunger
Power	Compressed spring	Compressed spring	Compressed spring
Components and Materials	Conform with ISO 10993 part 1 for fluid path	Conform with ISO 10993 part 1 for fluid path	Conform with ISO 10993 part 1 for fluid path
Safety/Alarms	None except Fluid level indicator to monitor flow	None except plunger movement monitors flow	None except plunger movement monitors flow
Packaging	Tyvek-sealed tray containing pump, administration sets, and accessories. Flow restrictors, and y- connector sets, may be separately packaged	Tyvek-sealed tray containing pump, administration sets, and accessories. Flow restrictors, and y connector sets, may be separately packaged	Tyvek-sealed tray containing pump, administration sets, and accessories. Flow restrictors, y-connector sets, and catheter sets may be separately packaged

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 3 0 2005

Sgarlato Laboratories, Incorporated
C/O Michael McDougall, Ph.D.
Regulatory Affairs
Michann Partners LLC
2315 South Bascom Avenue Suite #200
Campbell, California 95008

Re: K043204
Trade/Device Name: Sgarlato PainFree Pump; Sgarlato Pain Control Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: February 24, 2005
Received: March 16, 2005

Dear Dr. McDougall:

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,

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

K043204

Indications for Use

510(k) Number (if known): K043204

Device Name: Sgarlato PainFree Pump; Sgarlato Pain Control Infusion Pump

Indications For Use:

The Sgarlato PainFree Pump is a single use, general purpose infusion device intended to provide continuous infusion of medication (such as local anesthetics or corticosteroids) directly into a target site for the purpose of pain relief. Infusion may be carried out via percutaneous, subcutaneous, and epidural routes. The PainFree Pump may be used to provide continuous infusion of a local anesthetic directly into an intraoperative site for postoperative management of pain following surgery. It is suitable for use as an ambulatory device. It is not intended for vascular drug delivery, hyperalimentation, or the delivery of blood or blood products.

Prescription Use Yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (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)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K043204