

2/24/99

K980751

510(k) Submission, Sabratek 4040 Infusion Pump

Sabratek, Niles, IL 60714

The following is a Summary of the Sabratek 4040 Infusion Pump substantial equivalence and safety and efficacy.

Classification Name: Infusion Pump
 Common/Usual Name: Infusion Pump
 Proprietary Name: Sabratek 4040 Infusion Pump
 Classification: Class II Medical Device
 Performance Standards: No applicable performance standards
 Have been issued under Section 514 of
 The Food, Drug and Cosmetic Act.
 Predicate Device: Sabratek 6060 HOMERUN® Volumetric Infusion Pump,
 K941984 and Sabratek 3030 Infusion Pump, K914581.

ELEMENT OF COMPARISON	SABRATEK 4040 PUMP	SABRATEK 6060 PUMP	SABRATEK 3030 PUMP
510(k)#		K941984	
Pump type	Linear Peristaltic	Rotary Peristaltic	Linear Peristaltic
Intended use(s)	Intravenous, Intra-arterial, subcutaneous & intracavity infusions	Intravenous, Intra-arterial, subcutaneous & intracavity infusions	
Administration Sets -Captive Standard Set -Captive 1.2 Micron Filter -Captive .22 Micron Filter -Standard Sabraset -Approved Competitive Sets	Yes Yes Yes Yes Yes	Yes Yes Yes No No	No No No Yes Yes
Free Flow Clamp -Anti Free Flow Clamp (Set) -Free Flow Clamp (Pump)	Yes Yes	Yes No	No Yes
Specific Drug, biologic use: -Blood/Blood Products	Blood/Blood Products	No	No
Components -Pumping Mechanism -Battery -Pressure Sensor -Ultrasound Air In Line	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes
Pumping mechanism	Linear Peristaltic	Rotary Peristaltic	Linear Peristaltic
Power Requirements	Switchable 90-132/138-264Vac 50/60 hz	12 - 18 Volts DC, 50 ma maximum	110V AC, 10 watts, 50/60 hz
Battery Life Recharge Time	6-6.5 hrs at 125 ml/hr 24 hrs	25 hrs at 125 ml/hr N/A	7-8 hrs at 125 ml/hr 24 hrs

Fluid Path Material: -Tubing -Spike -Check Valve -Silicone Rubber Tubing -1.2 or .22 Micron Filter -MLL (Male Luer Lock) -Connecting Barbs -Y-Site -Fluid Bag -Solvent bonding Solution	PVC ABS N/A Silicone Rubber Modified acrylic/supor ABS Acrylic Acrylic N/A Cyclohexanone	PVC ABS N/A Silicone Rubber Modified acrylic/supor ABS Acrylic Acrylic EVA Cyclohexanone	PVC ABS Silicone Rubber Modified acrylic/supor ABS Acrylic Acrylic N/A Cyclohexanone
Infusion Parameters: -Flow Rate Range -Flow Accuracy, % -KO rate -Infusion volume limit -Prime/purge mode	0.1 – 999 ml/hr +/- 5% 0.1 – 10 ml/hr 0.1 – 999.9 ml No	0.1 400 ml/hr +/-6% 0.1- 10 ml/hr 1.1 - 9999 ml Yes	1- 999 ml/hr +/-5% 1 - 9 ml/hr 1 - 999 ml No
Profiles -Continuous -Auto-Ramp -Intermittent -25 Period -PCA	Yes Yes Yes Yes No	Yes Yes Yes Yes Yes	Yes Yes Yes Yes No
Alarm Type: -Air-In-Line -Cassette Not Installed -Check Internal 9V Batteries -Complete XX ml (or mg) -Door Open -Down Occlusion -Empty Bag or Up Occlusion -Empty Battery -Hold -Low Bag -Low Battery -Malfunction -Move Tubing -Nicad Depleted -Rate Exceeds Microset Limits -Release/Remove PCA Cord -Reprogram -Stuck Key -High Pressure -Low Pressure	Audible, LCD N/A N/A Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD None Audible, LCD Audible, LCD Audible, LCD Audible, LCD N/A N/A Audible, LCD Audible, LCD Audible, LCD Audible, LCD	Audible, LCD Audible, LCD None Audible, LCD Audible, LCD None Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD	Audible, LCD N/A N/A Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD None Audible, LCD Audible, LCD Audible, LCD Audible, LCD N/A N/A Audible, LCD Audible, LCD Audible, LCD Audible, LCD Audible, LCD
External Communication Capability	Yes	Yes	Yes

Indications	Provides controlled delivery of fluids, blood and blood products and can be used in enteral, epidural, subcutaneous, arterial and intravenous applications.
Contraindications	The Sabratek 4040 Infusion Pump is contraindicated for use with a blood set, other than those specifically designated as such and manufactured by Sabratek Corporation.
Non-Clinical Tests	Non-clinical tests included accuracy testing and comparison with Sabratek's stated accuracy claim and recording of data.
Conclusions	The Sabratek 4040 Infusion Pump is equivalent in safety and efficacy to its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Mr. Charles P . Gill
Manager, Regulatory Affairs
Sabratek Corporation
8111 North St.Louis Avenue
Skokie, Illinois 60076

Re: K980751
Trade Name: Sabratek 4040 Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 13, 1998
Received: December 3, 1998

Dear Mr. Gill

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

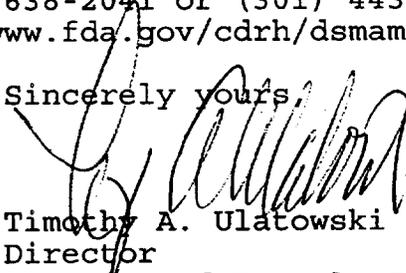
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known)

Device Name: Sabratek 4040 Infusion Pump

Indications for use: Provide controlled delivery of fluids, blood and blood products and can be used in enteral, epidural, subcutaneous, arterial and intravenous applications.

Prescription Device. Federal Law (US) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Salvador Cuervo (Optional Format 1-2-96)
(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K980751