

JUN 10 1998

K980957

510(K) SUMMARY

SUBMITTER'S NAME AND ADDRESS: LocalMed, Inc.
1820 Embarcadero Road
Palo Alto, CA 94303

PHONE: (650) 843-6770
(650) 843-6771 fax

CONTACT PERSON: Aaron Kaplan, MD

DATE SUMMARY PREPARED: March 11, 1998

DEVICE TRADE NAME: Kaplan-Simpson InfusaSleeve™ II

DEVICE COMMON NAME: Catheter, infusion

DEVICE CLASSIFICATION NAME: Catheter, continuous flush

SUBSTANTIALLY EQUIVALENT DEVICE(S): InfusaSleeve™ IIa, InfusaSleeve™ II

DEVICE DESCRIPTION AND FUNCTION:

The Kaplan-Simpson InfusaSleeve™ II is a multi-lumen catheter consisting of a proximal infusion port, a proximal shaft, and a main catheter shaft with a distal infusion region. An entry port for balloon and guide wire access is located at the proximal end of the main shaft which is proximal to the infusion region. See Figure 1.

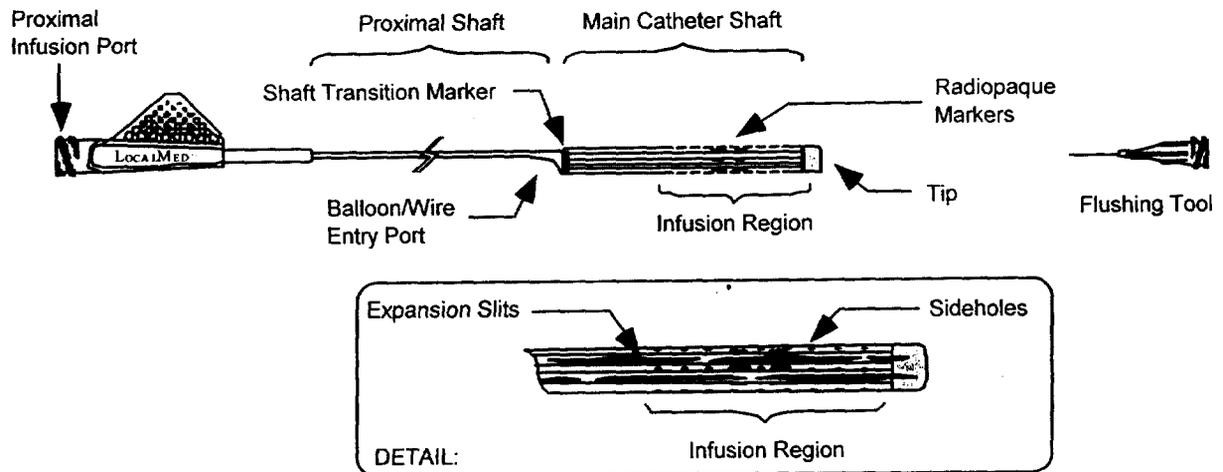


Figure 1

The infusion region consists of four separate infusion lumens each with multiple sideholes. Radiopaque markers are located within the infusion region. Infusion solution is delivered through the proximal infusion port, through the four infusion lumens and exits through the sideholes into the coronary vasculature. A standard luer adapter allows for attachment of a syringe with a manometer or equivalent to the proximal infusion port. A flushing tool is included to facilitate flushing the main catheter shaft through the distal tip. The InfusaSleeve II is designed to track over standard dilatation catheters.

INTENDED USE:

The InfusaSleeve II is intended to infuse fluids such as heparinized saline, diagnostic agents such as contrast media, and thrombolytic agents such as urokinase into the coronary vasculature. The catheter is designed for use with a commercially available dilatation catheter to facilitate selective and subselective access and regional infusion.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

	PREDICATE		
	InfusaSleeve IIa	InfusaSleeve II	InfusaSleeve II
General indications:	General intravascular use, delivery of therapeutic solutions. Selective and sub-selective controlled infusion of solutions.	same	same
Usage:	Single use, disposable	same	same
How supplied:	Sterile, non-pyrogenic	same	same
Sterilization method:	100% Ethylene Oxide (EtO) sterilized	same	same
Materials:			
Infusion port:	Polycarbonate	same	same
Proximal shaft:	Stainless Steel, Nylon	same	same
Main shaft & Tip:	Nylon	same	same
Lubricious coating:	Silicone	same	same
Radiopaque marker:	Gold/Stainless steel	same	same
Hard Stop:	Pellethane	same	same
Transition marker	Stainless steel	-	same
Support elements:	Stainless steel	same	same
Design & Construction:			
Catheter configuration:	Introduced co-axially over a dilatation device. Infusion through peripheral lumens.	same	same
Shaft configuration:	Multi-lumen device. Central lumen accommodates dilatation device. Four opposing peripheral infusion lumens.	same	same
Infusion region:	Nine-delivery side holes per peripheral lumen.	same	same
Infusion side hole diameter:	28µm	40µm	40µm
Mode of operation:			
Solution delivery mode:	Solution delivery via the peripheral lumen side holes into the vasculature.	same	same
Maximum proximal infusion pressures:	50 psig	50 psig	100 psig

PREDICATE			
	InfusaSleeve IIa	InfusaSleeve II	InfusaSleeve II
		<u>Flow Rate (mL/min)</u>	
Infusion Pressure (psig)			
5	5	5	3
15	10	10	7
30	15	15	13
40	17	20	17
50	20	25	20
60	-	-	24
70	-	-	27
80	-	-	31
90	-	-	34
100	-	-	38
Vascular access:	Percutaneous	same	same
Tracking mechanism:	Over-the-balloon	same	same
Size:			
Total length:	1.4 m	same	same
Working length:	1.3 m	same	same
Infusion region length:	2 cm	same	same
Outer diameter:	1.5 - 2.1 mm	same	same
Inner diameter:	0.9 - 1.5 mm	same	same
Compatibility:			
Max balloon diameter	4.0 mm	3.5 mm	4.0 mm
Max balloon catheter shaft size:	3.8 Fr	3.5 Fr	3.8 Fr
Guiding catheter:	Standard	same	same
Infusion port fitting:	ISO 594 luer conical fitting	same	same
Radiopacity:	via Radiopaque distal markers	same	same

NONCLINICAL TESTS:

Material biocompatibility, bond joint tensile strengths, infusion pathway fatigue, burst pressure, flexural strength, infusate flow, torque strength, histology, balloon tracking fatigue, tip expansion resistance, and in-vivo animal evaluations.

TEST CONCLUSIONS:

The test results verified that the InfusaSleeve II performance is equivalent to, or exceeds the predicate InfusaSleeve II device performance.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aaron Kaplan, MD
Localmed, Inc.
1820 Embarcadero Road
Palo Alto, CA 94303

Re: K980957
Trade Name: Kaplan-Simpson Infusasleeve II (100) or IS-2 (100)
Regulatory Class: II
Product Code: KRA
Dated: March 11, 1998
Received: March 16, 1998

Dear Mr. Kaplan:

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 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). 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 through 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 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) 594-4618. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (K) Number (if known): N/A

Device Name: InfusaSleeve II (IS-2)

Indications for Use:

The InfusaSleeve II is intended to infuse fluids such as heparinized saline, diagnostic agents such as contrast media, and thrombolytic agents such as urokinase into the coronary vasculature. The catheter is designed for use with a commercially available dilatation catheter to facilitate selective and subselective access and regional infusion.

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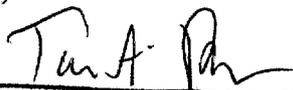
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K900957