

K972175

510(K) SUMMARY

AUG 28

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

PHONE: (415) 843-6770
(415) 843-6771 fax

CONTACT PERSON: Edwin Lee

DATE SUMMARY PREPARED: June 6, 1997

DEVICE TRADE NAME: Kaplan-Simpson InfusaSleeve™ IIa

DEVICE COMMON NAME: Catheter, infusion

DEVICE CLASSIFICATION NAME: Catheter, continuous flush

SUBSTANTIALLY EQUIVALENT DEVICE(S): InfusaSleeve™ II

DEVICE DESCRIPTION AND FUNCTION:

The Kaplan-Simpson InfusaSleeve™ IIa 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.

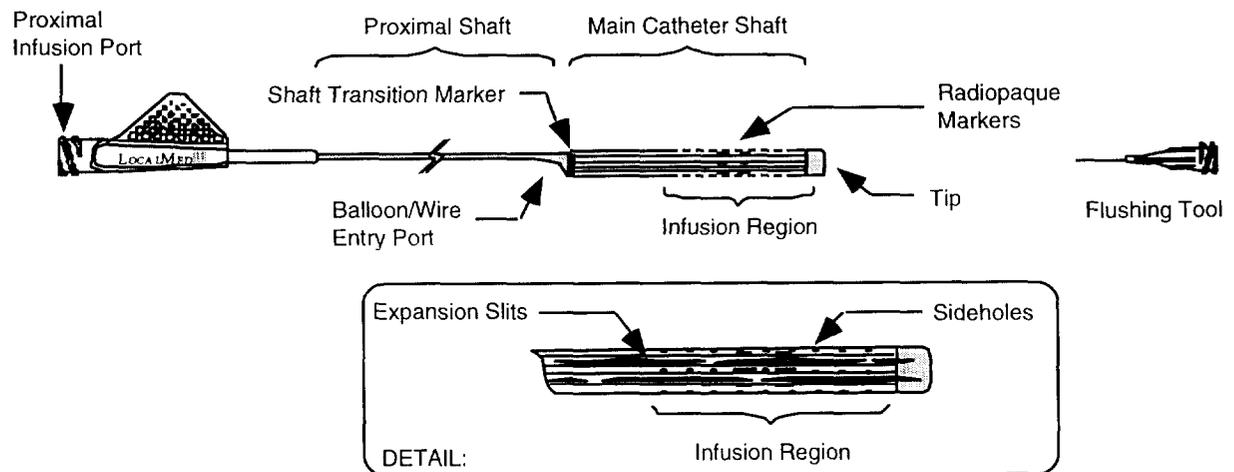


Figure 1

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 IIa is designed to track over standard dilatation catheters.

INTENDED USE:

The InfusaSleeve IIa 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:

	InfusaSleeve II	InfusaSleeve IIa (premarket notification)
General indications:	General intravascular use, delivery of therapeutic solutions. Selective and sub-selective controlled infusion of solutions.	General intravascular use, delivery of therapeutic solutions. Selective and sub-selective controlled infusion of solutions.
Usage:	Single use, disposable	Single use, disposable
How supplied:	Sterile, non-pyrogenic	Sterile, non-pyrogenic
Sterilization method:	100% EtO sterilized	100% EtO sterilized
Materials:		
Infusion port:	Polycarbonate	Polycarbonate
Proximal shaft:	Stainless Steel, Nylon	Stainless Steel, Nylon
Main shaft & Tip:	Nylon	Nylon
Lubricious coating:	Silicone	Silicone
Radiopaque marker:	Gold/Stainless steel	Gold/Stainless steel
Support elements:	Stainless steel	Stainless steel
Design & Construction:		
Catheter configuration:	Introduced coaxially over a dilatation device. Infusion through peripheral lumens.	Introduced coaxially over a dilatation device. Infusion through peripheral lumens.
Shaft configuration:	Multi-lumen device. Central lumen accommodates dilatation device. Four opposing peripheral infusion lumens.	Multi-lumen device. Central lumen accommodates dilatation device. Four opposing peripheral infusion lumens.
Distal infusion region:	Nine delivery sideholes per peripheral lumen. 0.04 mm sidehole diameters.	Nine delivery sideholes per peripheral lumen. 0.028 mm sidehole diameters.
Mode of operation:		
Solution delivery mode:	Solution delivery via the peripheral lumen sideholes into the vasculature.	Solution delivery via the peripheral lumen sideholes into the vasculature.
Maximum proximal infusion pressures:	50 psig	50 psig
Vascular access:	Percutaneous	Percutaneous
Tracking mechanism:	Over-the-balloon	Over-the-balloon
Size:		
Total length:	1.4 m	1.4 m
Working length:	1.3 m	1.3 m

	InfusaSleeve II	InfusaSleeve IIa (premarket notification)
Infusion region length:	2 cm	2 cm
Outer diameter:	1.5 - 2.1 mm	1.5 - 2.1 mm
Inner diameter:	0.9 - 1.5 mm	0.9 - 1.5 mm
Compatibility:		
Max balloon diameter	3.5 mm	4.0 mm
Max balloon catheter shaft size:	3.5 Fr	3.8 Fr
Guiding catheter:	Standard	Standard
Infusion port fitting:	ISO 594 luer conical fitting	ISO 594 luer conical fitting
Radiopacity:	via Radiopaque distal markers	via Radiopaque distal markers

NONCLINICAL TESTS:

Material biocompatibility, bond joint tensile strengths, infusion pathway fatigue, burst pressure, infusate flow, torque strength, histology, and *in-vivo* animal evaluations.

TEST CONCLUSIONS:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Ed Lee
Director, Regulatory Affairs
and Quality Assurance
LocalMed
1820 Embarcadero Road
Palo Alto, California 94303

AUG 28 1997

Re: K972175
Kaplan-Simpson InfusaSleeve™ IIA
Regulatory Class: II (two)
Product Code: KRA
Dated: June 6, 1997
Received: June 9, 1997

Dear Mr. Lee:

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.

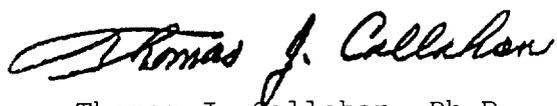
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market 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 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 pre-market 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) 594-4648. 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,



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): K972175

Device Name: InfusaSleeve IIa (IS-2a)

Indications for Use:.....

The InfusaSleeve IIa 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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IF NEEDED)

Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)