



USER: GRAY, ILKA K (ixg)

FOLDER: K022869 - 72 pages (FOI:08007474)

COMPANY: I-FLOW CORP. (IFLOW)

PRODUCT: PUMP, INFUSION (FRN)

SUMMARY: Product: SOAKER CATHETER

DATE REQUESTED: Fri Nov 05 24:00:00 2010

DATE PRINTED: Tue Jan 04 07:25:06 2011

Note: Releasable Version

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SEP 20 2002

K022869

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

August 23, 2002

Submitter: I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Contact: Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation

Trade Name: Soaker Catheter

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Existing Device: Soaker Catheter (K991543 and K994374)

Device Description: The Soaker Catheter has a closed end tip with multiple holes arranged radially along the lateral surface along the infusion segment at the distal end of the device. A membrane in the inner diameter of the catheter promotes even distribution along the infusion segment. This special 510(k) proposes a slight design change that has the membrane along the outside diameter of the catheter instead of the inside diameter.

Technology Comparison: The new Soaker Catheter utilizes the exact same technology for promoting even distribution along the infusion segment.

Conclusion: The Soaker Catheter is substantially equivalent to the existing Soaker Catheter.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2002

Ms. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K022869
Trade/Device Name: Soaker Catheter
Regulation Number: 880.5725
Regulation Name: Accessories, Infusion Pump
Regulatory Class: II
Product Code: MRZ and FRN
Dated: August 23, 2002
Received: August 29, 2002

Dear Ms. Noehre:

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 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

A handwritten signature in black ink, appearing to read "Timothy A. Ulatowski". The signature is fluid and cursive, with a large initial "T" and "U".

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

Enclosure

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K022869

Device Name: Soaker Catheter

Indications For Use:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, percutaneous or perineural.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cuccone

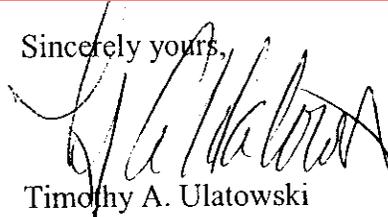
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022869

(b) (4)

(b)(4)

Sincerely yours,



Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

2



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 20 2002

Ms. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K022869
Trade/Device Name: Soaker Catheter
Regulation Number: 880.5725
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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.

/

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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

Enclosure

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K022869

Device Name: Soaker Catheter

Indications For Use:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, percutaneous or perineural.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cucurite

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022869

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Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 29, 2002

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: SHANE NOEHRE

510(k) Number: K022869
Received: 29-AUG-2002
Product: SOAKER CATHETER

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

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K022869

CDRH SUBMISSION COVER SHEET

Date of Submission: August 23, 2002

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
<input type="checkbox"/> Original submission <input type="checkbox"/> Modular submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA Supplement	<input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report	<input checked="" type="checkbox"/> Original submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated <input type="checkbox"/> Additional information: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated	<input type="checkbox"/> Pre-IDE meeting <input type="checkbox"/> Pre-PMA meeting <input type="checkbox"/> Pre-PDP meeting <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify):
IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<input type="checkbox"/> Original submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	<input type="checkbox"/> Original submission <input type="checkbox"/> Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: I-Flow Corporation Establishment registration number: 2026095

Division name (if applicable): Phone number (include area code): (b)(4) (b)(4)

Street address: 20202 Windrow Drive FAX number (include area code): (b)(4) (b)(4)

City: Lake Forest State / Province CA Country: U.S.A.

Contact name: (b)(4) (b)(4)

Contact title: Executive Vice President and CEO Contact e-mail address: (b)(4) (b)(4)

RECEIVED
AUG 23 9 07 AM '02
FDA/CDRH/DOE/DW/C

Section C Submission correspondent (if different from above)

Company / Institution name: I-Flow Corporation Establishment registration number: 2026095

Division name (if applicable): Phone number (include area code): (b)(4) (b)(4)

Street address: 20202 Windrow Drive FAX number (include area code): (b)(4) (b)(4)

City: Lake Forest State / Province: CA Country: U.S.A.

Contact name: Shane Noehre, RAC

Contact title: Director, Regulatory Affairs Contact e-mail address: (b)(4) (b)(4)

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SK 1

AR II

Section D1 Reason for Submission — PMA, PDP, or HDE		
<input type="checkbox"/> New device <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement <input type="checkbox"/> Process change <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor <input type="checkbox"/> Report submission: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent
Section D2 Reason for Submission — IDE		
<input type="checkbox"/> New device <input type="checkbox"/> Addition of institution <input type="checkbox"/> Expansion / extension of study <input type="checkbox"/> IRB certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of study <input type="checkbox"/> Withdrawal of application <input type="checkbox"/> Unanticipated adverse effect <input type="checkbox"/> Notification of emergency use <input type="checkbox"/> Compassionate use request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continuing availability request <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing process <input type="checkbox"/> Protocol – feasibility <input type="checkbox"/> Protocol – other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current investigator <input type="checkbox"/> Annual progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final	<input type="checkbox"/> Response to FDA letter concerning: <input checked="" type="checkbox"/> Conditional approval <input type="checkbox"/> Deemed approved <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting
Section D3 Reason for Submission — 510(k)		
<input type="checkbox"/> New device <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Other reason (specify):	<input type="checkbox"/> Change in technology <input checked="" type="checkbox"/> Change in design	<input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process

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Section E Additional Information on 510(k) Submissions					
Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data: <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement	
1 BSO	2	3	4		
5	6	7	8		
Information on devices to which substantial equivalence is claimed:					
510(k) Number	Trade or proprietary or model name			Manufacturer	
1 K991543	1 Soaker Catheter (originally identified as IntraOp Catheter)			1 I-Flow Corporation	
2 K994374	2 Soaker Catheter			2 I-Flow Corporation	
3	3			3	
4	4			4	
5	5			5	
6	6			6	
Section F Product Information — Applicable to All Applications					
Common or usual name or classification name: Catheter, Conduction, Anesthesia					
Trade or proprietary or model name				Model number	
1 Soaker Catheter				1 various	
2				2	
3				3	
4				4	
5				5	
FDA document numbers of all prior related submissions (regardless of outcome):					
1	2	3	4	5	6
7	8	9	10	11	12
Data included in submission: <input type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials					
Section G Product Classification — Applicable to All Applications					
Product code BSO	C.F.R. Section: 868.5120			Device class: <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification panel: Anesthesiology					
Indications (from labeling): See Indications for Use page in submission.					

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number:	
Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2026095	
<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name: I-Flow Corporation		Establishment registration number: 2026095	
Division name (if applicable):		Phone number (include area code): (b)(4)(b)(4)	
Street address: 20202 Windrow Drive		FAX number (include area code): (b)(4)(b)(4)	
City: Lake Forest	State / Province: CA	Country: U.S.A.	
Contact name: Shane Noehre, RAC			
Contact title: Director, Regulatory Affairs		Contact e-mail address: (b)(4)(b)(4)	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2026095	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA establishment registration number: 2026095	
<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer		<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler	
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	
Contact name:			
Contact title:		Contact e-mail address:	

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SPECIAL 510(k): Device Modification

August 23, 2002

Via Federal Express

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ – 401)
9200 Corporate Blvd.
Rockville, Maryland 20850

RECEIVED
Aug 29 9 47 AM '02
FDA/CORR/ODE/DRG

Reviewing Staff:

In accordance with §510(k) of the Federal Food, Drug, and Cosmetic Act and in conformance with Title 21 CFR §807.81, I-Flow Corporation is submitting this premarket notification for the *Soaker Catheter* prior to the introduction into interstate commerce for commercial distribution.

I-Flow intends to make a design change to our existing *Soaker Catheter*. The existing (unmodified) *Soaker Catheter* has been cleared under the following two 510(k)s: K991543 and K994374.

No changes will be made to the indications for use, sterilization, fundamental scientific technology, packaging or labeling (except for clarification).

All questions and/or comments concerning this document should be made to:

Shane Noehre
Director, Regulatory Affairs

Sincerely,

(b) (6)
(b)(6)

Shane Noehre, RAC
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Dr
Lake Forest, CA 92630

Tel: (b) (4) (b)(4) Fax: (b) (4) (b)(4)
e-mail: (b) (4) (b)(4)

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Appendix A – Risk Assessment for the Soaker Catheter (DCD1190A)

Appendix B – Soaker Catheter Drawings

Appendix C – Soaker Catheter Labeling

Appendix D – Predicate Regulatory Documentation

Appendix E – Summary of Safety and Effectiveness

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**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(j))**

I certify that, in my capacity as the Executive Vice President and COO of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the Soaker Catheter are truthful and accurate and that no material fact has been omitted.

		(b)(6)	Signature
		(b)(6)	
		Executive Vice President and COO	
		(b)(4)	Title
		(b)(4)	
		I-Flow Corporation	
		Dated	
		8/28/02	
		Dated	
		Company	

Premarket Notification (510(k) Number)

20

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K022869

Device Name: Soaker Catheter

Indications For Use:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, percutaneous or perineural.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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DECLARATION OF CONFORMITY

As required by the risk analysis, all verification and validation activities will be performed by designated individuals and the results shall demonstrate that the predetermined acceptance criteria are met prior to the introduction into interstate commerce for commercial distribution.

The I-Flow Corporation manufacturing facilities are in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

(b)(6)
(b)(6) 8/28/02
Dated

(b)(6) (b)(6) 8/28/02
Signature Dated

(b)(4)
(b)(4)
Executive Vice President and COO
I-Flow Corporation

(b)(4)
(b)(4)
Vice President of Engineering / R&D
I-Flow Corporation

Verification and Validation activity will ensure the device meets the requisite design specifications and acceptance criteria and shall include the following:

1. Even Distribution over Infusion Segment: min/max (b)(4) distribution.
2. Flow Rate Impact: Meet or exceed the performance of current design.
3. Tensile Strength: Meet or exceed current design and comply with (b)(4)
4. Flexural Strength: Meet or exceed current design.
5. Elongation: Meet or exceed performance of current design.
6. Attachment Security: Meet or exceed current design.
7. Hub Leakage: Meet or exceed current design.
8. Catheter Burst Pressure: Meet or exceed current design.
9. Kink Resistance: Meet or exceed current design.
10. Material Compatibility: per the Risk Assessment and (b)(4)
11. Labeling: per section 9.0 of this submission.
12. Package Integrity: per section 11.0 of this submission.
13. Sterility: per section 12.0 of this submission.
14. In-process Inspection (includes incoming and final): per the Risk Assessment and Verification/Validation.

Reference Documents

1. Risk Assessment for the Soaker Catheter (DCD1190A)

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1.0 GENERAL INFORMATION

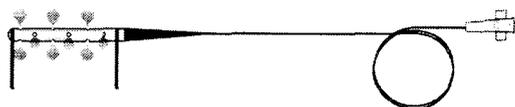
1.1 Purpose of Submission

- 1.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow intends to make a device modification to our own legally marketed device.
- 1.1.2 The change affects the *Soaker Catheter*. The following changes are proposed:
- 1.1.2.1 A change to a stronger material formulation of the catheter body. The material is still a (b) (4) (b)(4) (b)(4) from the same vendor, (b) (4) (b)(4).
- 1.1.2.2 Moving the infusion segment membrane from the inner diameter to the outer diameter of the catheter.
- 1.1.2.3 Add additional catheter markings.

1.2 Statement of Equivalence

- 1.2.1 The existing (unmodified) Soaker Catheter has been cleared under the following 510(K)s:
- K991543 – the initial Soaker Catheter premarket notification (originally identified as the IntraOp Catheter); and
 - K994374 – added the 5 inch infusion segment model.
- 1.2.2 No changes will be made to the indications for use, sterilization method, fundamental scientific technology, packaging or labeling (except for clarification).
- 1.2.3 Common Name: Anesthetic Catheter
- 1.2.4 Classification Name: Catheter, Conduction, Anesthesia
- 1.2.5 Product Code: BSO
- 1.2.6 Device Classification: Class II, 868.5120
- 1.2.7 Medical Specialty: Anesthesiology

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTONS



(not to scale)

2.1 Existing (unmodified) Description of Device

- 2.1.1 The Soaker Catheter consists of two main components, the catheter body and the infusion segment membrane.
- 2.1.2 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.
- 2.1.3 The length of the multiple holes roughly corresponds to the infusion segment which equals the length of the (b) (4) (b)(4) membrane.

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- 2.1.4 The [redacted] membrane along the [redacted] of the catheter allows drug delivery to be distributed across the full length of holes rather than just the first few holes.
- 2.1.5 The catheter has two markings. One marking at the distal end tip and one marking at the start of the infusion segment.
- 2.1.6 The distal end of the catheter will be placed in the surgical site prior to final closure or along a nerve using a special needle (typically known as a nerve block procedure).
- 2.1.7 In surgical wound applications, the wound would be closed, allowing the end of the catheter to remain within the wound.
- 2.1.8 The proximal end of the catheter contains a bonded hub which attaches to an infusion pump such as I-Flow's elastomeric infusion pump.
- 2.1.9 The catheter is suitable for use as an ambulatory device and is intended for use in hospitals, home environments or alternate care sites.

3.0 PROPOSED DESIGN CHANGES

3.1 Catheter Body:

- 3.1.1 A change to a stronger material formulation of the catheter body. The material will remain the same type of [redacted] (b)(4) from the same vendor, [redacted] (b)(4).
- 3.1.2 The new material will increase the performance of the following properties of the catheter:
 - 3.1.2.1 [redacted] (b)(4) will increase; and
 - 3.1.2.2 [redacted] (b)(4) will increase.
- 3.1.3 This design change will not decrease any performance of the device.

3.2 Infusion Segment Membrane

- 3.2.1 A change to the [redacted] (b)(4) from the [redacted] (b)(4) of the catheter [redacted] (b)(4) of the [redacted] (b)(4) of the catheter.
- 3.2.2 This proposed design change represents a natural evolution based on our original concept designs and patent. It allows for [redacted] (b)(4) [redacted] (b)(4) and [redacted] (b)(4) along the [redacted] (b)(4).
- 3.2.3 This design change will not decrease any performance of the device.

3.3 Catheter Markings:

- 3.3.1 A change to the markings is to [redacted] (b)(4) [redacted] (b)(4). The markings are identical in material composition to the existing markings.
- 3.3.2 An additional [redacted] (b)(4) [redacted] (b)(4) will be added along the [redacted] (b)(4) and each stripe will be [redacted] (b)(4) [redacted] (b)(4).
- 3.3.3 This design change will not decrease any performance of the device.

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4.0 MODELS

- 4.1 The Soaker Catheter will consist of the same two models currently in use:
- 4.1.1 Soaker Catheter (b)(4) has a (b)(4) (b)(4) and
- 4.1.2 Soaker Catheter (b)(4) has a (b)(4) (b)(4)
- 4.2 The Soaker Catheter may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market by FDA).
- 4.2.1 Examples of kit components include the following:
- 4.2.1.1 (b)(4) (b)(4) introducer needle (b)(4) (b)(4) of various lengths;
- 4.2.1.2 (b)(4) (b)(4) syringe; or
- 4.2.1.3 (b)(4) (b)(4) dressing.
- 4.2.2 The kit configuration option is the same as the predicate device per K994374.

5.0 COMPONENTS AND MATERIALS

All components and materials will comply with ISO 10993-1 for biocompatibility. All the materials are of the same type as the existing (unmodified) Soaker Catheter.

- 5.1 Catheter Body: The material will remain a (b)(4) (b)(4)
- 5.2 Infusion Segment Membrane: The material will remain either (b)(4) (b)(4) (b)(4) (b)(4)
- 5.3 Catheter Markings: The material will remain the same.

6.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

- 6.1 **Standard Operating Conditions:**
- Infusion Segment Distribution: (b)(4) distribution, min/max (b)(4) (b)(4)
- Flow Rate Impact: no restriction for (b)(4) (b)(4)
- Tensile Strength: \geq ISO (b)(4) requirement
- Flexural Strength: equivalent to predicate device
- Elongation: $>$ (b)(4) and \leq (b)(4)
- Attachment Security: \geq (b)(4)
- Hub Leakage: no leaks at (b)(4) psi for (b)(4) (b)(4)
- Catheter Burst Pressure: no rupture at (b)(4) psi for (b)(4) (b)(4)
- Residual Volume: $<$ 1 ml

7.0 BIOCOMPATIBILITY SPECIFICATIONS

- 7.1 Biocompatibility testing is in conformance with ISO 10993 Part 1 for all fluid path components based on intended application of the device prior to market distribution.

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8.0 INDICATIONS FOR USE

8.1 There is no change to the indications for use.

9.0 LABELS AND LABELING

9.1 The only change to the labeling will be for clarification if necessary.

9.2 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

9.3 The Soaker Catheter Directions for Use labeling:

9.3.1 Provides comprehensive directions for preparation and use for the Soaker Catheter.

9.3.2 Describes the routes of administration as it relates to intended use.

9.3.3 Contains warning information.

9.3.4 Contains the prescription statement required under 801.109 (b)(1).

9.3.5 Includes the specifications of the Soaker Catheter.

9.4 Identification labels and labeling

9.4.1 There will be no change to the product identification labeling for the Soaker Catheter other than new part numbers and maybe cosmetic differences.

9.5 Packaging labels

9.5.1 Contains the prescription statement required under 801.109 (b)(1).

10.0 STANDARDS

10.1 Although the Soaker Catheter is not intended for intravascular use, where applicable, the Soaker Catheter shall comply with ISO (b)(4) (b)(4)

(b)(4) (b)(4)

11.0 PACKAGING

11.1 There is no change in the packaging. Packaging is in conformance with the standard EN 868-1 (Packaging Materials and Systems for Medical Devices which are to be Sterilized).

12.0 STERILIZATION

12.1 There is no change in the sterilization methods.

13.0 COMPARISON TO THE EXISTING (UNMODIFIED) SOAKER CATHETER

13.1 Indications for Use

13.1.1 No change in intended use.

13.2 Fundamental Scientific Technology

13.2.1 No change in technology.

13.2.2 The Soaker Catheter utilizes the same technology for distributing medication (b)(4) (b)(4)

13.3 Operational Specifications

13.3.1 No change in specifications other than improved performance.

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13.4 No change in sterilization, packaging, or labeling (except for clarification).

13.5 Materials

13.5.1 The materials used in the new Soaker Catheter design are the same type as the predicate device covered in the previous premarket notifications, K991543 and K994374.

13.6 **Conclusion:**

13.6.1 The new Soaker Catheter design will exceed or match the performance requirements of the existing (unmodified) Soaker Catheter.

13.6.2 I-Flow Corporation believes that the new Soaker Catheter design is substantially equivalent to the existing (unmodified) Soaker Catheter.

Appendix A
Risk Assessment

(b)(4)

(b)(4)

5.0 RISK EVALUATION

(b)(4)

(b)(4)

6.0 RISK CONTROL

(b)(4)

(b)(4)

PAGE 2 OF 5

CONTROL COPY

REV. A

DCD/10

(b)(4)

(b)(4)

7.0 RISK MANAGEMENT REPORT

(b)(4)

(b)(4)

PAGE 3 OF 5

CONTROL COPY

REV. A

DD/SH

Table 1 - Failure Mode and Effect Analysis (FMEA) for Catheter Body

Risk Assessment for Soaker Catheter Improvements
(b)(4)
Rev. A

(b)(4)

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Table 2 - Failure Mode and Effect Analysis (FMEA) for (b)(3) Fiber

(b)(4)

(b)(4)

Appendix B
Drawings

DWG NO. (b)(4) SH 1 REV A

Revisions

Zone	Rev.	Description	Date	Chg. by	Ck. by

(b)(4)

ITEM NO.	QTY	INDENT NO.	PART OR IDENTIFYING NO.	NOMENCLATURE OR DESCRIPTION
5	1			
4	1			
3	1			
2	1			
1	1			

(b)(4)

PARTS LIST

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
 DECIMALS ANGLES
 .XX ± 0.01 ± 0°.30
 .XXX ± 0.005

NO INFORMATION CONCERNING REVISIONS OR MODIFICATIONS SHALL BE REPRODUCED OR REFERRED TO IN ANY DOCUMENTS, EXCEPT AS AUTHORIZED BY WRITTEN AUTHORIZATION FROM I-FLOW CORPORATION.

I-FLOW I-FLOW CORPORATION
 Lake Forest, CA 92650

KIT SOAKER
 CATHETER 6.5

APPROVALS: DRAWN _____ DATE _____
 CHECKED _____
 ENC. _____

SIZE PAGE CODE DWG NO. (b)(4) REV A
 B

DO NOT SCALE DRAWING
 SCALE NONE FILE NAME SHEET 1 OF 1

(b)(4)



NOTES: UNLESS OTHERWISE SPECIFIED

36

Revisions

1

2

3

4



(b) (4)

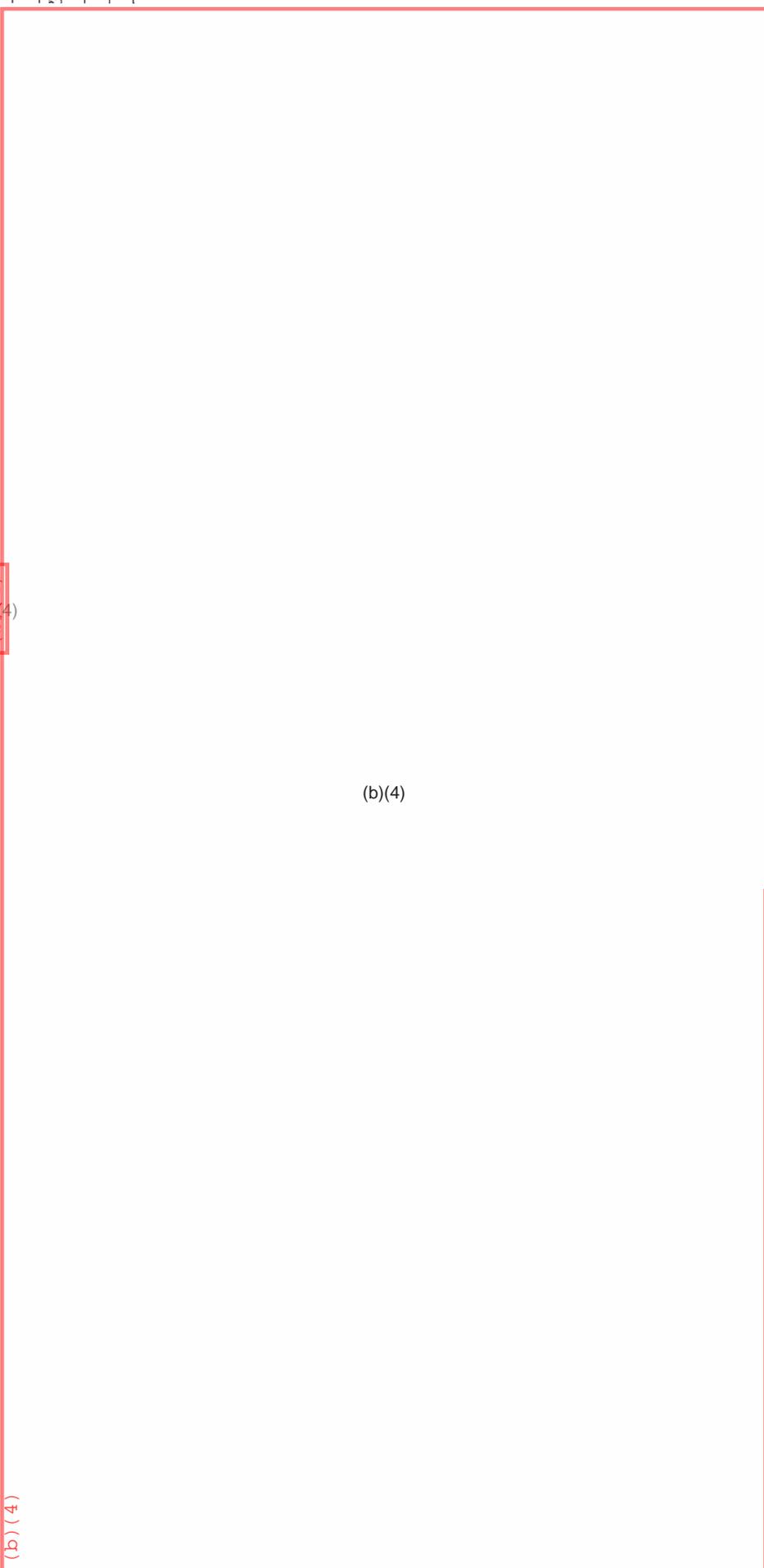
(b) (4)

(b)(4)

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE: DECIMALS .XX ±0.01 .XXX ±0.005 ANGLES ±1/2°		APPROVALS DRAWN Kevin Forrest CHECKED ENG.		DATE 8/12/2002	
MATERIAL		TITLE CATHETER ASSEMBLY (b) (4)		I-FLOW CORPORATION Lake Forest, CA 92830	
FINISH		SIZE CAGE CODE DWG NO (b) (4)		REV I	
DO NOT SCALE DRAWING		SCALE FILE NAME NTS 3001065i.iam		SHEET 1 OF 1	

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DWG NO (b)(4) SH. REV.



(b)(4)

ITEM NO.		QTY	INDENT NO.	PART OR IDENTIFYING NO.	NOMENCLATURE OR DESCRIPTION	
					PARTS LIST	
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE:		I-FLOW CORPORATION Lake Forest, CA 92630				
DECIMALS .XX ±0.01 ±0.30		CATHETER, 20ga				
ANGLES .XXX ±0.005		2.5 inch, 2-STRIPE				
MATERIAL		APPROVALS		SIZE ENG CODE		
FINISH		DATE		DWG NO		
		4-28-02		(b)(4)		
		DRAWN K.FORREST		SCALE 1/1.5		
		CHECKED <i>[Signature]</i>		FILE NAME: 1120766A.DWG		
		ENG.		SHEET 1 OF 1		
		QA/QC				
DO NOT SCALE DRAWING						

(b)(4)

(b)(4)

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DWG NO (b)(4) SH 1 REV A

Revisions

Zone	Rev.	Date	Chg. by	Ck. by

(b)(4)

(b)(4)

ITEM NO.	QTY	INDENT NO.	RECD	PART OR IDENTIFYING NO.	NOMENCLATURE OR DESCRIPTION
6	1				
5	1				
4	1				
3	1				
2	1				
1	1				

(b)(4)

PARTS LIST

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES
TOLERANCES ARE:
DECIMALS ANGLES
.XX ± 0.01 ± 0°.30
.XXX ± 0.005

I-FLOW I-FLOW CORPORATION
Lake Forest, CA 92630

KIT, SOAKER
CATHETER 12.5

APPROVALS: DRAWN _____ CHECKED _____ ENG. _____ QA/QC _____

DATE _____

SIZE PAGE CODE DWG NO (b)(4) REV A

SCALE NONE FILE NAME: SHEET 1 OF 1

(b)(4)

NOTES: UNLESS OTHERWISE SPECIFIED

- 4.
- 3.
- 2.
- 1.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES ARE: DECIMALS .XX ±0.01 .XXX ±0.005 ANGLES ±1/2°		APPROVALS		DATE	 I-FLOW CORPORATION Lake Forest, CA 92630
MATERIAL		DRAWN	Kevin Fortesl	3/12/2002	
FINISH		CHECKED	ENG.		
DO NOT SCALE DRAWING		SCALE		FILE NAME: 3001082e.iam	NTS
		SIZE		CAGE CODE	DWG NO
		B			(b)(4)
		REV			E
		SHEET		1	OF 1

Parts List

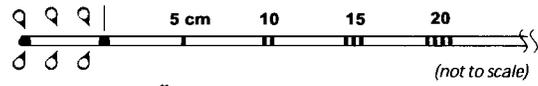
4 3 2 1

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Appendix C
Labeling

43

Improved Soaker with Depth Markings



ON-Q
Post-Op
Pain Relief

Soaker™ Catheter

1303290A

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Models:

Soaker Catheter 6.5 and Soaker Catheter 12.5

Soaker™ Catheter

Directions for Use

INDICATIONS FOR USE

The Soaker Catheter is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, percutaneous or perineural.

The Soaker Catheter may be used with I-Flow's PainBuster, ON-Q or Nerve Block Infusion Systems.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED.

THE ON-Q SOAKER EXPANSION KIT IS STERILE AND NON-PYROGENIC.

SINGLE USE ONLY. DO NOT RESTERILIZE.

CAUTIONS

- Do not exceed maximum fill volume of pump.
- Use of vasoconstrictors such as Epinephrine or adrenaline is not necessary and may not be recommended for continuous infusions.
- Medications used with this system should be administered in accordance with instructions provided by the drug manufacturer.
- Do not withdraw catheter through needle because of the possible danger of shearing.
- Use only smooth-edged atraumatic clamps or forceps.
- After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.
- Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

WARNINGS

- Assure that the catheter is not in a vein or artery. Even if aspirations for blood are negative, intravascular penetration is still possible. Visual inspection, test dosing and patient monitoring are recommended - refer to drug manufacturer's package insert.
- Do not suture catheter.

CONTRAINDICATIONS

- The Soaker Catheter is not intended for intravenous, intra-arterial or epidural drug delivery.

SUGGESTED CATHETER MAINTENANCE

The catheter should be maintained in accordance with standard hospital protocols.

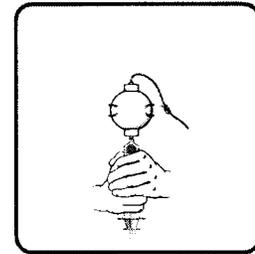
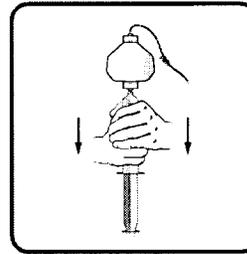
DIRECTIONS FOR USE

Use Aseptic Technique

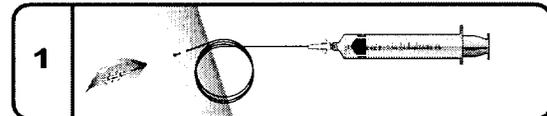
Filling the I-Flow Elastomeric Pump

- Close clamp on tubing.
- Uncap the fill port. Do not discard cap.
- Attach filled syringe to the fill port and inject fluid into pump (refer to diagram below). Repeat as necessary.

- Do not exceed maximum fill volume of pump.
- Replace fill port cap.
- Label with the appropriate pharmaceutical and patient information.
- Open the clamp and remove the distal end cap to prime the pump (up to 15 minutes). Allow the medication to fill the entire tubing and luer connector. When all air has been removed from the tubing and connector close the clamp until ready to use.



Priming The Catheter



Proper priming of the catheter and pump tubing is very important. Any trapped air in the catheter may create air locks which may affect proper catheter performance.

Attach a syringe filled with medication to the catheter connector. Slowly prime the catheter until medication infuses out all the holes along the length of the catheter. Make sure no air is trapped in the catheter.

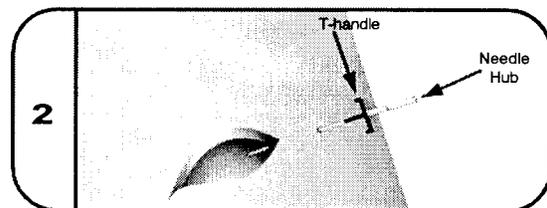
Placing the Catheter

To insure infusion segment is within the wound site, the black catheter marking must not be visible outside the puncture site.

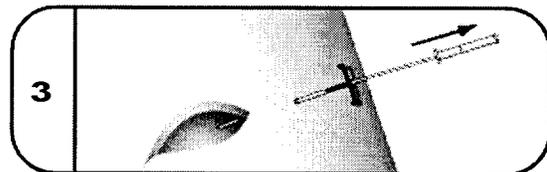
NOTE Remove needle guard from the introducer while holding T-handle.

Do not apply excessive pressure to the T-handle.

Grip only the needle hub during insertion.



Insert introducer needle (with bevel up) through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site.



While holding the T-handle, withdraw the introducer needle.



Insert the marked end of the catheter through the opening of the T-handle introducer into the wound site.

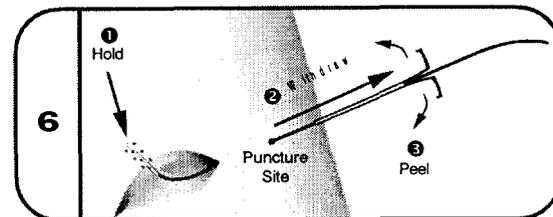
WARNING: Assure that the catheter tip is not in a vein or artery. Do not suture catheter.

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CAUTION: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement to ensure that occlusion will not occur during use and that catheter removal will not be impeded.



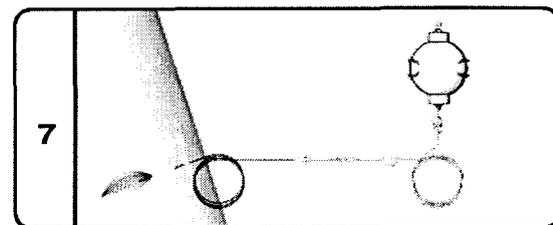
Drug infusion occurs between black catheter marking and black marked tip (see Table 1).



Advance catheter into wound site until white catheter segment is visible.

While holding catheter tip 1 withdraw T-handle from puncture site 2 and split the introducer sheath and peel it away from the catheter 3.

Place the catheter within wound site to desired position. Ensure that entire infusion segment is within wound site.



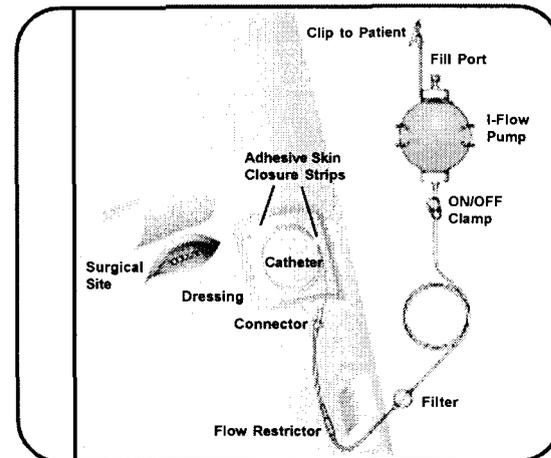
Attach the catheter connector to the pump tubing. Open the pump clamp to begin infusion.



Secure catheter by coiling close to the insertion site.

Apply occlusive dressing (not included) over insertion site and coiled catheter, keeping separate from wound. Do not cover filter with dressing.

Secure flow restrictor to skin. The flow restrictor must not be in contact with cold therapy pads.



The Soaker system may contain an E-Clip and/or Carry Case. If using the E-Clip, attach to the top of the pump. Secure the pump with the E-Clip or Carry Case.

Infusion is complete when the pump is no longer inflated.

REMOVING THE CATHETER

CAUTION: The catheter should be easy to remove. If significant resistance is felt, then it is advisable to wait 30 to 60 minutes and try again. The patients body movements may relieve the catheter to allow easier removal. Check the distal end of the catheter for black marking to ensure the entire catheter was removed.

Table 1

20 GA	Soaker Catheter 6.5		Soaker Catheter 12.5	
	Centimeters	Inches	Centimeters	Inches
Infusion Segment	6.5	2.5	12.5	5.0

Dimensions are approximate. Catheter is radiopaque.

For more information on the Soaker Catheter please call our Customer Service Department or visit us on the web at:

1.800.448.3569 or 949.206.2700

www.i-flowcorp.com

www.AskYourSurgeon.com

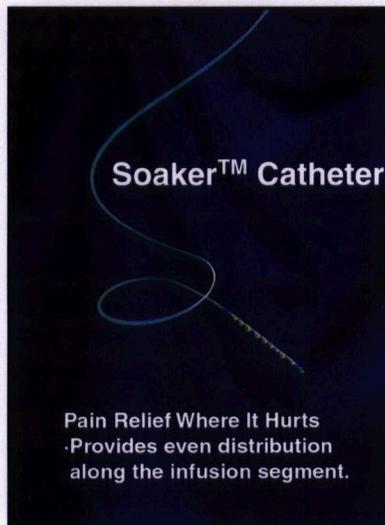
MANUFACTURED BY:

I-FLOW CORPORATION
 LAKE FOREST, CA 92630
 U.S.A.

CE European Representative:
 MPS Medical Product Service GmbH
 Borgasse 20, 35619 Braunfels
 Germany
0123

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
 U.S. Patents: D324,911; 5,080,652; 5,284,481. U.S. and Foreign Patents Pending.
 * ON-Q is an I-Flow Corporation trademark registered with the U.S. Patent and Trademark Office.
 † Soaker is a trademark of I-Flow Corporation.

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Appendix D
Predicate Regulatory Documentation

[CDRH](#)
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Device CATHETER, CONDUCTION, ANESTHETIC
Medical Specialty Anesthesiology
Product Code BSO
Device Class 2
510(k) Exempt? No
Regulation Number 868.5120
Third Party Review Eligible for *Accredited Persons Expansion Pilot Program*

[Accredited Persons and Third Party Program Information](#)

Accredited Persons

- CALIFORNIA DEPARTMENT OF HEALTH SERVICES
- CITECH
- ENTELA, INC.
- N.V. KEMA
- TUV AMERICA, INC.
- TUV RHEINLAND OF NORTH AMERICA, INC.
- UNDERWRITERS LABORATORIES, INC.

(Database Updated August 5, 2002)

[Accessibility](#)

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U.S. Food and Drug Administration - Center for Devices and Radiological Health

Code of Federal Regulations

Title 21 - Food and Drugs Revised as of April 1, 2002

Popular
Items

Interacting
w/CDRH

Special
Interest

Premarket

Postmarket

Rad.
Health

Topic
Index

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR868.5120]

[Page 282]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 868--ANESTHESIOLOGY DEVICES--Table of Contents

Subpart F--Therapeutic Devices

Sec. 868.5120 Anesthesia conduction catheter.

(a) Identification. An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics into a patient and to provide continuous regional anesthesia.

(b) Classification. Class II (performance standards).

CDRH Home Page FDA Home Page Search Comments

Accessibility

50

OCT 25 1999

K991543

SUMMARY OF SAFETY AND EFFECTIVENESS

Trade Name: ***Intra Op Catheter***

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Classification Panel: Anesthesiology

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq., R.A.C.
Vice President of Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Statement of Equivalence

- 1.1.1 The ***Intra Op Catheter*** is substantially equivalent to the (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed Internation FETH-R_KATH catheter.
- 1.1.2 The ***Intra Op Catheter*** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the ***Intra Op Catheter***

- 2.1.1 The ***Intra Op Catheter*** is identical to the Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the exception of a hollow fiber in the inner diameter of the distal end of the catheter.
 - 2.1.1.1 ***Intra Op Catheter*** is manufactured by TFX using their current plastic formulation.
 - 2.1.1.2 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

¹SE = Substantially Equivalent

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- 2.1.2 The catheter package may contain a "T" Peel catheter over needle or a catheter connector (e.g. Touhy Borst) in addition to the catheter defined herein.

2.2 Product Configuration

2.2.1 The Catheter

- 2.2.1.1 The catheter is designed to be distributed in two basic configurations.

- 2.2.1.1.1 As shown in the catheter drawing (Dwg. No. 1120741 found in Appendix A), Detail G depicts the proximal end of the catheter with a catheter connector (Touhy Borst type) attached.

- 2.2.1.1.2 An alternate configuration with a bonded or insert molded luer lock catheter connector is also shown in the drawing.

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1

4.0 BIOLOGICAL SPECIFICATIONS

4.1

- 4.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

- 4.3 The *Intra Op Catheter* is categorized as follows:

- 4.3.1 Device Category: External Communicating Device.
 - 4.3.2 Body Contact: Tissue/Bone/Dentin Communicating
 - 4.3.3 Contact Duration: Prolonged (24 hours to 30 days).

5.0 CHEMICAL AND DRUG SPECIFICATIONS

5.1 Compatibility

- 5.1.1 There are no specific drugs referenced in the labeling for the *Intra Op Catheter*.

- 5.1.2 The *Intra Op Catheter* is intended for use with general local anesthetics and narcotic medications.

5.2 Drug Stability

- 5.2.1 There are no drugs included in the *Intra Op Catheter*.

6.0 INTENDED USE

- 6.1 The *Intra Op Catheter* is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and nerve trunks outside of the epidural space. Routes of administration may be either, intraoperative, intramuscular, subcutaneous or percutaneous.

- 6.2 The catheter is single patient use only.

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7.0 LABELS AND LABELING

7.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

8.0 STANDARDS

8.1 There are currently no standards established for anesthetic catheters.

9.0 PACKAGING

9.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

10.0 STERILIZATION INFORMATION

10.1 The method of sterilization is Ethylene oxide gas or radiation

11.0 COMPARISON TO LEGALLY MARKETED DEVICES

11.1 The *Intra Op Catheter* is substantially equivalent to the (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed Internation FETH-R_KATH catheter.

11.2 Device Descriptions

11.2.1 Comparisons

11.2.1.1 The device under review and its predicates are closed end with lateral/radial side holes.

11.2.2 Materials

11.2.2.1 The *Intra Op Catheter's* fluid path materials are in conformance with ISO 10993 Part 1.

11.2.3 Based upon the data presented in this section, I-Flow Corporation has determined that the Intra Op Catheter is substantially equivalent to the named predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stanley E. Fry
Vice President
Regulatory Affairs/Quality Assurance
I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Re: K991543
Trade Name: Intraop Catheter
Regulatory Class: II
Product Code: MEB
Dated: September 3, 1999
Received: September 7, 1999

Dear Mr. Fry:

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 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

54

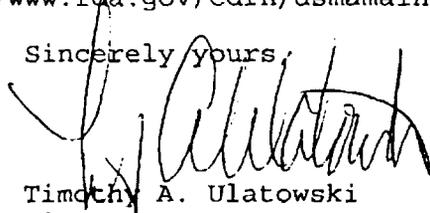
Page 2 - Mr. Fry

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) 594-4692. 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

55

510(k) Number (if known): K991543

Device Name: Intra Op Catheter

Indications for Use:

The *Intra Op Catheter* is intended to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and nerve trunks outside of the epidural space. Routes of administration may be either, intraoperative, intramuscular, subcutaneous or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
~~Division of Cardiovascular, Respiratory,
and Neurological Devices~~
510(k) Number K991543

WMS

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____



(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991543

Page ii

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MAR - 3 2000

K 994374

Summary of Safety and Effectiveness

Trade Name: **Soaker Catheter**

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Classification Panel: Anesthesiology

All questions and/or comments concerning this document should be made to:

Stanley E. Fry
Vice President of Regulatory and Quality

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Telephone: 949.206.2700
Fax: 949.206.2600

1.0 GENERAL INFORMATION

1.1 Statement of Equivalence

- 1.1.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter (K991543), (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries), (3) B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter (K981329).
- 1.1.2 The **Soaker Catheter** package may include components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation) such as an introducer needle or dressing.

2.0 PHYSICAL SPECIFICATIONS AND DESCRIPTIONS

2.1 Description of the Soaker Catheter

- 2.1.1 The **Soaker Catheter** is identical to the predicate IntraOp Catheter (K991543). This premarket notification adds an additional model to the Soaker Catheter family of catheters.
- 2.1.2 The **Soaker Catheter** consists of a Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries Medical) with the insertion of a hollow fiber membrane in the inner diameter of the distal end of the catheter.
 - 2.1.2.1 The catheter has a closed end tip with multiple holes arranged radially along the lateral surface at the distal end of the device.

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2.2 Product Configuration

2.2.1 The following **Soaker Catheter** models will be available:

- 2.2.1.1 S0605: 20 GA with 6.5 cm (2.5 in.) infusion segment (K991543).
- 2.2.1.2 S1205: 20 GA with 12.5 cm (5.0 in.) infusion segment.
- 2.2.1.3 Each of the catheter sizes will be available as a separate catheter with a currently marketed catheter connector (a Touhy Borst type is an example of any acceptable connector) or an attached luer lock connector. The connectors will meet the ANSI specifications conical connectors.

2.2.2 The **Soaker Catheter** may consist of a kit that includes components that are legally marketed (either pre-amendment devices or devices that have been granted permission to market via premarket notification regulation).

2.2.2.1 Examples of the kit components include the following:

- 2.2.2.1.1 Teleflex Medical (TFX) "T" peel catheter over needle 18 GA X 2 ½" - 3 ½" or
- 2.2.2.1.2 Johnson & Johnson Biocclusive dressing.

2.2.3 The **Soaker Catheter** may be used in I-Flow's Pain Management Systems such as K982946 and K984502.

3.0 BIOLOGICAL SPECIFICATIONS

3.1 All materials in the catheter are identical in formulation to materials currently being used in other products with the same or similar uses and have a long history of use in those devices.

3.2 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.

4.0 CHEMICAL AND DRUG SPECIFICATIONS

4.1 Drug Compatibility and Stability

- 4.1.1 There are no specific drugs referenced in the labeling for the **Soaker Catheter**.
- 4.1.2 There are no drugs included in the **Soaker Catheter**.

5.0 INTENDED USE

5.1 The **Soaker Catheter** is intended to be used as follows:

- 5.1.1 With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
- 5.1.2 As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.

5.2 The catheter is single patient use only.

6.0 LABELS AND LABELING

- 6.1 I-Flow Corporation believes the proposed labels and labeling, where appropriate, meets the requirements of 21 CFR Part 801 as it relates to a determination of intended use and adequate directions for use.

7.0 STANDARDS

- 7.1 There are currently no standards established for anesthetic catheters.

8.0 PACKAGING

- 8.1 The catheter is packaged in either a Tyvek pouch or a form/fill/seal tray.

9.0 COMPARISON TO LEGALLY MARKETED DEVICES

- 9.1 The **Soaker Catheter** is substantially equivalent to the (1) I-Flow IntraOp Catheter submitted in K991543, (2) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (3) the B. Braun Perifix Set (K813186) and (4) the Epimed International FETH-R_KATH catheter.

9.2 Device Descriptions

9.2.1 Comparisons

- 9.2.1.1 This submission is intended to notify the Federal Food and Drug Administration that I-Flow Corporation intends to add an additional model to the family of **Soaker Catheters** formerly referred to as the IntraOp Catheter (K991543). The new model is virtually identical to the predicate 2.5 inch Soaker Catheter except that the new model will have a 5.0 inch infusion segment.

- 9.2.1.2 All the catheters provide a catheter connector device similar to a Touhy Borst connector or a molded luer lock connector.

- 9.2.2 Based upon the data presented in this section, I-Flow Corporation has determined that the **Soaker Catheter** is substantially equivalent to the named predicate devices.



MAR - 3 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Stanley E. Fry
Vice President of Regulatory and Quality
I-Flow Coproration
20202 Windrow Drive
Lake Forest, California 92630

Re: K994374
Trade Name: Soaker Catheter
Regulatory Class: II
Product Code: FRN
Dated: October 23, 1999
Received: December 27, 1999

Dear Mr. Fry:

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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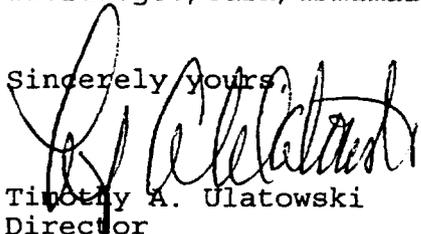
Page 2 -Mr. Fry

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) 594-4690. 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

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510(k) Number (If known): K994374

Device Name: Soaker Catheter

Indications for Use:

The *Soaker Catheter* is intended to be used as follows:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative or percutaneous.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Patricia Cucurto

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K994374

Page 111

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Appendix E
Summary of Safety and Effectiveness

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SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

August 23, 2002

Submitter: I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Contact: Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation

Trade Name: Soaker Catheter

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Existing Device: Soaker Catheter (K991543 and K994374)

Device Description: The Soaker Catheter has a closed end tip with multiple holes arranged radially along the lateral surface along the infusion segment at the distal end of the device. A membrane in the inner diameter of the catheter promotes even distribution along the infusion segment. This special 510(k) proposes a slight design change that has the membrane along the outside diameter of the catheter instead of the inside diameter.

Technology Comparison: The new Soaker Catheter utilizes the exact same technology for promoting even distribution along the infusion segment.

Conclusion: The Soaker Catheter is substantially equivalent to the existing Soaker Catheter.

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**SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: KD22869

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	✓	
Table of Contents.	✓	
Truthful and Accurate Statement.	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement.	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***	✓	

- * - May not be applicable for Special 510(k)s.
- ** - Required for Class III devices, only.
- *** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	✓	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

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is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- * - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No
 Reviewer: Yael Yant
 Concurrence by Review Branch: Yael Yant
 Date: AUG 30 2002

//

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

9-20-02

Memorandum

From: Reviewer(s) - Name(s) Yael Yamth

Subject: 510(k) Number K022869

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance? YES NO

Is this device subject to the Tracking Regulation? YES NO

Was clinical data necessary to support the review of this 510(k)? YES NO

Is this a prescription device? YES NO

Was this 510(k) reviewed by a Third Party? YES NO

Special 510(k)? YES NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed p. 3
(required for originals received 3-14-95 and after)

A 510(k) summary ^{Appendix} OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after) p. 4

Animal Tissue Source YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

80 MRZ, Accessories, Infusion, Pump
Class II 880.5725 80 FRN, Pump, infusion

Review: Silvia Cuatrecasas 6HDB 9/20/02
(Branch Chief) (Branch Code) (Date)

Final Review: Chris L. J. Tu 9/20/02
(Division Director) (Date)

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

To: THE FILE

RE: DOCUMENT NUMBER K_022869_____

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.) Soaker catheter K991543 and K994374. (see p. 1 submission)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for the following: (as described on p.7 in submission sec 3) (b)(4), (b)(5) of the catheter body. The material will remain the same (b)(4), (b)(5) the same (b)(4), (b)(5) The change in location of the (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) The catheter (b)(4), (b)(5) (b)(4), (b)(5) from the start of the (b)(4), (b)(5) Also an additional (b)(4), (b)(5) will be added along the (b)(4), (b)(5). According to the sponsor (b)(4), (b)(5) (see email of 9/18/02). Discussed device changes with B. Burdick who suggested contacting the sponsor regarding the concentration of (b)(4), (b)(5) the stripes.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics. The sponsor states that the (b)(4), (b)(5)
(b)(4), (b)(5)
(b)(4), (b)(5)

5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis (Append A in submission)
 - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
 - c) A declaration of conformity with design controls. The declaration of conformity should include:
 - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. (see p. 5 of submission)
6. A **Truthful and Accurate Statement** (p. 3) , a **510(k) Summary** (Append E) **or Statement** and the **Indications for Use Enclosure** (p. 4) **(and Class III Summary for Class III devices)**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.

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Ufael J. Amth
(Reviewer's Signature)

9-20-02
(Date)

Comments The indications for use are the same as those cleared in K994374 regarding use of the catheter with certain kits. The routes of administration are the same as those in K991543 except intramuscular and subcutaneous is not listed but perineural is. These catheters have been indicated for use "close proximity outside the epidural space". They have not been considered under the procode of BSO, anesthesia conduction catheter, since those catheters are epidural catheters. Thus the soaker catheter is considered an accessory, infusion,, pump with Procode MRZ, Class II, 880.5725.

revised: 3/27/98

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Gantt, Gail

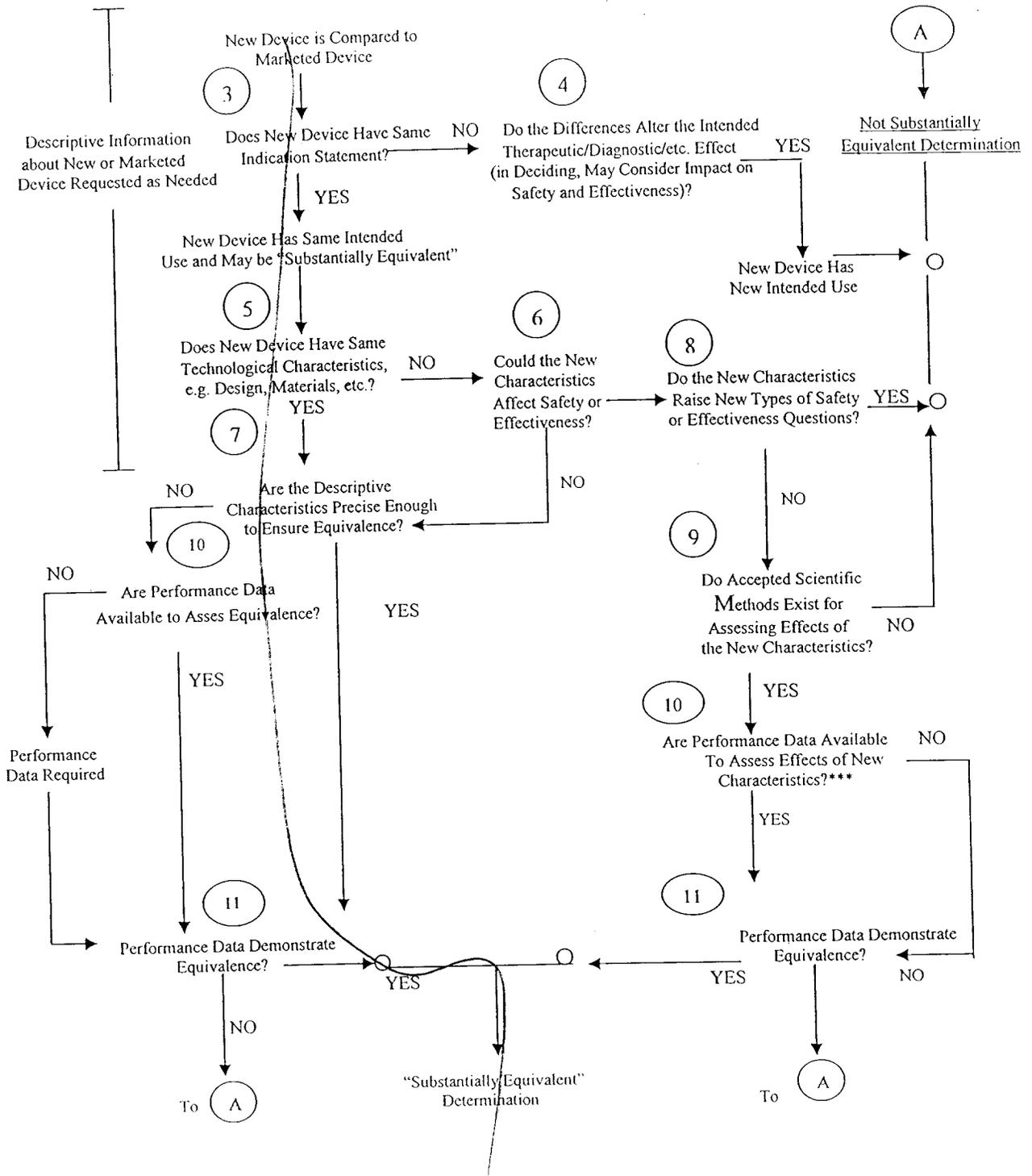
From: Bill Porter (b)(4) (b)(4)
Sent: Wednesday, September 18, 2002 2:10 PM
To: 'ggantt@cdrh.fda.gov'
Subject: Catheter (b)(4) (b)(4)

Gail;

(b)(4)
(b)(4)

Bill Porter, V.P., Engineering, R&D
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630
email: (b)(4)
phone: (b)(4)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- ❖ 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ❖❖ This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- ❖❖❖ Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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