



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 (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

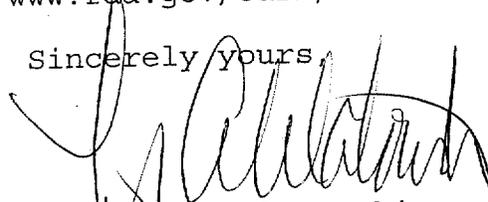
Page 2 - Mr. Fry

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

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~~

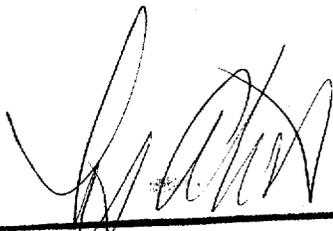
510(k) Number K991543

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

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Memorandum

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K991543/S1

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
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices N/A
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

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

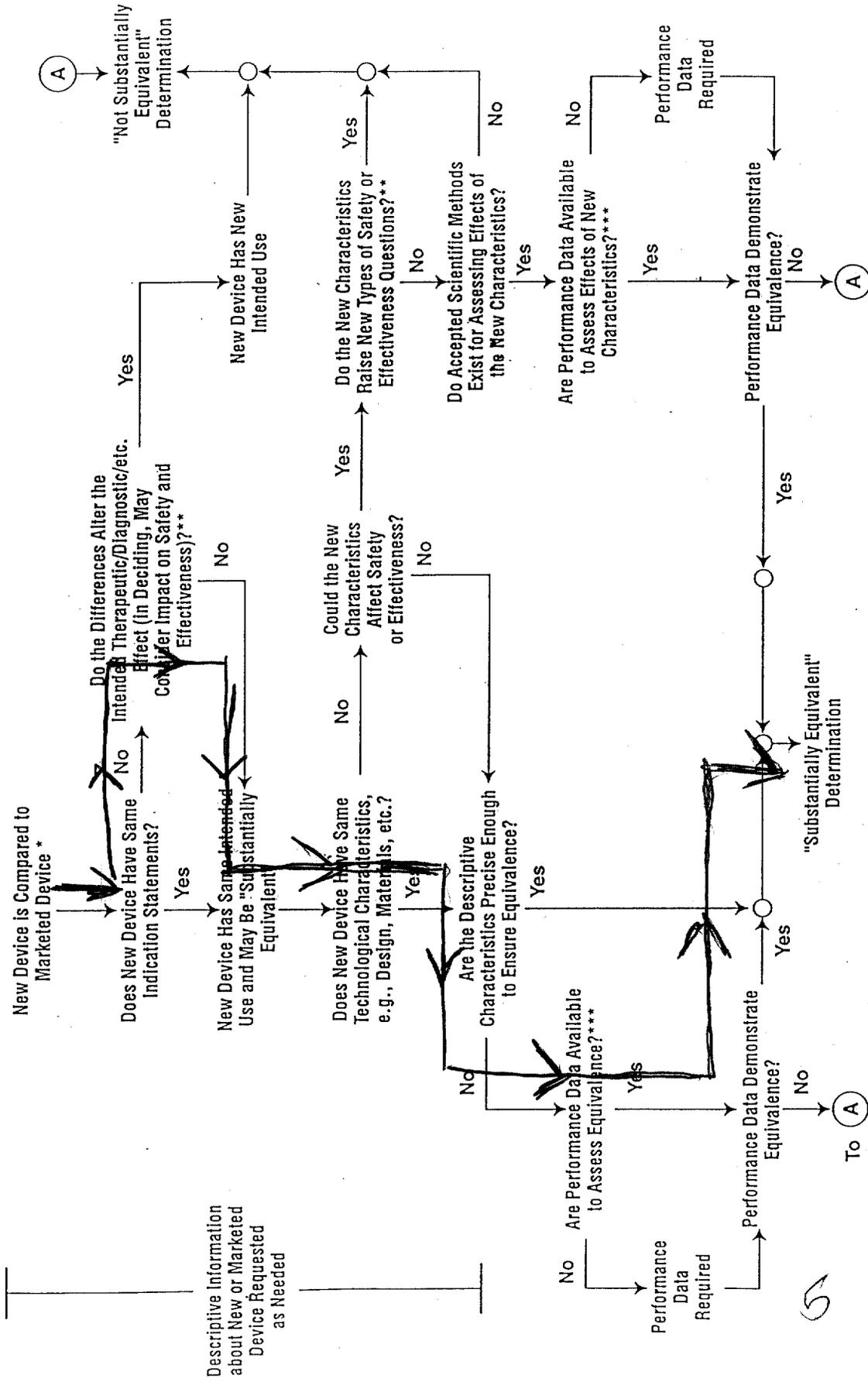
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

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

80 MEB; Class II 80 MAJ
880-5723 - Infusion Pump (accessory)
 Review: Patricia Cuervo AMPK3 10/22/99
 (Branch Chief) (Branch Code) (Date)
 Final Review: ~~Patricia Cuervo~~ [Signature] 10/23/99
 (Division Director) (Date)

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510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Approved or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K991543

Reviewer: William M. Burdick
 Division/Branch: DDIGD/GHDB

Device Name: Intra Op Catheter

Product To Which Compared (510(K) Number If Known): Please refer to 3L of attached "510(k) REVIEW".

		YES	NO	
1.	Is Product A Device	X		If NO = Stop
2.	Is Device Subject To 510(k)?	X		If NO = Stop
3.	Same Indication Statement?		X	If YES = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		X	If YES = Stop NE
5.	Same Technological Characteristics?	Y		If YES = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7.	Descriptive Characteristics Precise Enough?		X	If NO = Go To 10 If YES = Stop SE
8.	New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9.	Accepted Scientific Methods Exist?			If NO = Stop NE
10.	Performance Data Available?	X		If NO = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: SE

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

(Continued on Next Page.)

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1. *Intended Use:* Please refer to #2 of attached "510(k) REVIEW".

2. *Device Description:* Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

Please refer to #1 of attached "510(k) REVIEW".

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. *Explain why not a device:* N/A

2. *Explain why not subject to 510(k):* N/A

3. *How does the new indication differ from the predicate device's indication:* The new indication is for delivery of anesthetics or other pharmaceuticals to a wound site. The legally marketed, predicate catheters that are presently indicated for use with infusion pumps are intravascular not irrigation catheters.

4. *Explain why there is or is not a new effect or safety or effectiveness issue:* Essentially, these "irrigation" catheters should have fewer safety and effectiveness issues due to the fact that they will not be placed into the vasculature.

5. *Describe the new technological characteristics:* N/A

6. *Explain how new characteristics could or could not affect safety or effectiveness:* N/A

7. *Explain how descriptive characteristics are not precise enough:* Mechanical and performance testing not included in the submission were required for a final assessment.

8. *Explain new types of safety or effectiveness questions raised or why the questions are not new:* N/A

9. *Explain why existing scientific methods can not be used:* N/A

10. *Explain what performance data is needed:* N/A

11. *Explain how the performance data demonstrates that the device is or is not substantially equivalent:* The mechanical and performance testing later provided helped to demonstrate substantial equivalence.

ATTACH ADDITIONAL SUPPORTING INFORMATION

Please refer to the attached "510(k) REVIEW".

MEMO TO THE RECORD
510(K) REVIEW

K991543

DATE: October 19, 1999
FROM: William M. Burdick

DIVISION: DDIGD/GHDB

COMPANY NAME: I-Flow Corporation
DEVICE NAME: Intra Op Catheter

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The device which is the subject of this 510(k) is a catheter kit. The single-use, nonpyrogenic, sterilized [redacted] catheter will be marketed either as a separate catheter and connector (e.g., [redacted] type is an example of an acceptable connector) or as a catheter with [redacted] connector. Besides the possible catheter connector, the kit may contain a "T" Peel over-the-needle catheter introducer (18 ga. X 2½ - 3½ inches). Comparable predicate devices include the SideKick Infusion Kit (K990425) and The PainBuster (K980558), both from I-Flow Corporation.

The basic form of the Intra Op Catheter derives from the [redacted] Catheter [redacted] which is fabricated from [redacted] [please refer to I-Flow's response dated September 3, 1999]. This [redacted] catheter is modified by I-Flow with the [redacted]

[redacted] The tip of the catheter is [redacted] and multiple side-holes are [redacted] The [redacted] of the [redacted] the anesthetic drug to be distributed along the full length of holes rather than just the first few holes. The 20 ga. catheter is to be marketed as four models, the sole difference between models being the length (cm.): 52.5, 55, 57.5, and 60. The lengths of [redacted] lengths of the side holes, which differ with each model: 2.5 cm., 5 cm., 7 cm., and 10 cm.

As mentioned above, the kits will be sterilized [redacted] SAL of 10⁻⁶. Validation of the sterilization cycle will be [redacted] I-Flow states that [redacted]

Additional Information

Since anesthetics will be administered, I requested a consult ("REQUEST FOR CONSULTING REVIEW" dated June 21, 1999) from the Respiratory Branch of DCRND to ascertain the types of testing and other information needed to assess the safety and effectiveness of the catheter for the delivery of anesthetics. Mike Bazaral, M.D., Ph.D., sent a July 22, 1999, response in which some general flow rate and other basic supportive

information was solicited. Dr. Bazaraal stated in his response, which was repeated in our subsequent telephone conversation, that there should be no further need for review regarding the anesthesiology issues, since the issues he raised concerned general flow rate and similar engineering/physical science topics which were not confined to anesthesiology. From his review, three requests for additional information were addressed in our letter dated July 26, 1999.

I-Flow's September 3, 1999, response addressed all the issues raised (see our July 26, 1999, letter) in a satisfactory manner. It is important to note that I-Flow decided to limit the flow rate range to a maximum of 10 ml/hr as compared to the 200 ml/hr originally claimed. As a result of this change, I-Flow stated that this kit is similar to their family of elastomeric pump kits used in pain management systems. They cited their proprietary K984502: Nerve Block as a predicate.

2. INTENDED 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 the epidural space. The route of administration will only be surgical sites where the catheter may be positioned alongside a muscle or nerve.

3. DEVICE DESCRIPTION:

- A. Life-supporting or life-sustaining: No
- B. Implant (short-term or long-term): Yes
- C. Is the device sterile? Yes
If yes, is sterility information provided? Yes
- D. Is the device for single use? Yes
- E. Is the device for prescription use? Yes
If yes, is prescription labeling included? Yes
- F. Is the device for home use or portable? Yes
- G. Does the device contain drug or biological product as a component?
No
- H. Is this device a kit? Yes
If yes, and some or all of the components are not new, does the submission include a certification that these components were either preamendment or found to be substantially equivalent? Yes
- I. Software-driven: No
- J. Electrically Operated: No
- K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): No
- L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status:

KIT COMPARISON - K984502: Nerve Block by I-Flow Corporation.

CATHETER COMPARISON - K940202: Epidural Catheter by Teleflex Medical (TFX), originally submitted by Aries.

- M. Submission provides comparative specifications? Yes
comparative in vitro data? Yes

performance data? Yes
animal testing? No
clinical testing? No
biocompatibility testing? Yes

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

1. The subject catheter is similar in design and material composition to the stated predicate. For example, both are of a similar gauge size (about 20G) and are [redacted] with [redacted] side holes. Both are fabricated from [redacted]. The tensile strength of the [redacted]
2. The flow rate performance of the two catheters appeared to be equivalent.
3. Both kits provided a catheter connector component similar to [redacted] connector or a [redacted]

No new issues of safety or effectiveness exist for this device.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

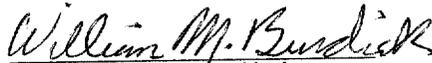
P. RECOMMENDATION:

I believe that this device is equivalent to: 80 MEB

Classification should be based on:

880.5725 - Infusion Pump (accessory)

Class: II


William M. Burdick
Biomedical Engineer

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

September 07, 1999

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: STANLEY E. FRY

510(k) Number: K991543
Product: INTRAOP CATHETER

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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



20202 Windrow Drive
 Lake Forest, CA 92630
 (800) 448-3569 (949) 206-2700
 Fax (949) 206-2600

K991543/S1

September 3, 1999

Food and Drug Administration
 Center for Devices and Radiological Health
 Document Mail Center (HFZ-401)
 9200 Corporate Boulevard
 Rockville, Maryland 20850

RECEIVED

7 SEP 99 08 51

FDA/CDRH/ODE/DHC

Re: K991543
Intra Op Catheter
Dated: April 30, 1999
Received: May 3, 1999

Dear M. Burdick:

This letter is in response to your inquiries on July 26, 1999 on the above referenced premarket notification A request for a 30-day extension of time was timely filed on August 24, 1999.

Modification:

I-Flow Corporation has taken the decision to limit the flow range to 10ml/hr as compared to the 200ml/hr originally claimed. This was done to bring the specifications of the catheter more in line with related pain management products already legally marketed by this firm. We do not intend to forego the higher flow rates, but in the interest of current market requirements, we wish to go forward with the modified flow range. We will resubmit to include the higher ranges following receipt of marketing authority based on this submission.

As a result of this change, the intended use of the device is as a kit component to our family of elastomeric pump kits used in pain management systems. Those pumps received premarket authorization under K982945 and K984502. As seen below, the intended use is modified to reflect this approach.

The subject pumps provide the following flow rates at an approximate pressure of PSI. When used with these pumps, the subject catheters deliver medication at the stated nominal rates. Further technical information is provided hereinafter in this response.

The specific changes required by the flow range modification, as compared to the original submission, are presented as follows:

Note: Unless otherwise stated, new language to be added/inserted is underlined.

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Re: K991543

1. 1.2 Statement of equivalence:

Paragraph 1.2.1 Insert in the first sentence as follows:

The **Intra Op Catheter** is substantially equivalent, when tested over the flow range of 0.5ml/hr to 10ml/hr, to the (1) Teleflex Medical Epidural Catheter.....

2. 3.0 Operational Specifications and Descriptions

Paragraph 3.2, delete reference to 5.0", 7.5", and 10" configurations

Paragraph 3.2.1, delete reference to 5,7, and 10 inches.

Responses :

Following are the responses to the inquiries as presented in your letter. The questions covered two areas, mechanical properties and anesthesia compatibility issues. The questions are treated in the same order as asked.

Mechanical properties:

Response to question 1:

Test conditions:

Prior to testing, the test catheters were subjected to [redacted] Sterilization. The typical sterilization process description is attached as Exhibit I.

At this time, final refinement of the production cycle, including validation [redacted] [redacted] Product will not be released for production prior to full validation.

Following sterilization the catheters have been maintained in a general laboratory environment with a temperature range of [redacted] and a humidity range of [redacted] [redacted].

(a) The requested data is presented as follows:

Tensile strength: (expressed as force) = [redacted]



Re: K991543

Test method: [redacted] samples were subjected to tensile force applied [redacted] to destruction. The pull rate of [redacted] was selected as a close approximation of the rate of withdrawal expected in actual use.

Flexural Strength:

Test method: [redacted] samples of the catheter were flexed [redacted]. The catheters were clamped [redacted] from the distal end and flexed at the clamp point resulting in a very small bend radius representing a severe condition. The flex profile was [redacted]. No failures were noted of either the catheter or [redacted].

Elongation: [redacted]

Test method: [redacted] samples were tested on an [redacted] with the pull rate set at [redacted]. In addition, [redacted] groups of [redacted] samples of catheter were tested under the same conditions. One group represented samples subjected to [redacted] and the other [redacted]. The [redacted] group demonstrated [redacted] elongation and the [redacted] group yielded [redacted]. This indicates a statistical insignificance between the two [redacted] methods.

(c) Attachment security: [redacted] Pull force

Test method: [redacted] each [redacted] connectors were subjected to a pull test at a pull rate of [redacted]. The [redacted] units yielded an average result of [redacted] with a std. deviation of [redacted], and the [redacted] version produced a result of [redacted] With a std. deviation of [redacted].

(b) The leakage at the hub: [redacted]

Test method: [redacted] test specimens were subjected to a pressure of [redacted] for a period of [redacted]. None of the samples demonstrated a leak. The test was conducted both in a [redacted] configuration. The test technique used involved pressurizing the catheter with [redacted].

(c) The catheter burst pressure is [redacted]



Re: K991543

Test method: This test was conducted in conjunction with the leak testing. As the test catheters were subjected to [redacted] it was concluded, in the absence of any failure, that the burst pressure exceeds [redacted]

In use, the maximum pressure that the catheter might be exposed to is [redacted] if used with an elastomeric infusion pump. Even if it were used with an electronic pump with a possible peak pressure of [redacted] a safety margin of [redacted] is still provided by the design.

Response to question 2:

The [redacted] is fashioned from [redacted]. This material has a [redacted]. Reference is made to the biocompatibility data provide in the original 510(k) submission in [redacted]. The material is a [redacted].

Exhibit II attached is a specification sheet of a [redacted].

If there is a breakage of the catheter *in situ*, said break will not present a biocompatibility hazard. (Reference the biocompatibility data provided in the underlying submission).

[redacted] the catheter the result will be a modification of the distribution pattern [redacted]. The medication will be delivered, [redacted].

In view of these two observations, no testing has been devised to determine breakage of the [redacted].

Response to question 3:

- a) The sentence - "Routes of administration may be either, intraoperative, intramuscular, subcutaneous, or percutaneous." - is stricken from the Indications for use.
- b) Paragraph 6.2 is stricken and replaced as follows:

The catheter is intended for use with I-Flow Corporation Elastomeric Pumps provided with PainBuster™ Infusion Kits, (K982946) and Nerve Block Infusion Kits, (K984502).



Re: K991543

Response to question 4:

[redacted] The catheter is manufactured from [redacted] --
It is manufactured by [redacted]

Response to request 5.

A sample of each style as requested is included herewith.

Anesthesia issues

Response to question 1.

The catheter provides flows as follows:

- 0.5 ml/hr
- 2.0 ml/hr
- 5.0 ml/hr
- 10.0 ml/hr

when used with the above referenced I-Flow Corporation elastomeric pumps, or equivalent. This represents the flows currently demanded by the market. Other specific flow rates, within the 0.5 ml/hr to 10.0 ml/hr range, may be indicated in the future, and it is the intent of I-Flow Corporation to provide those if so demanded by the market.

Response to question 2.

[redacted] samples of the catheter were subjected to flow distribution testing. The test involved delivering [redacted] such that the [redacted] of the [redacted] and the [redacted] delivered output [redacted]. The total amount collected from each sample was then [redacted]. The results, shown in Exhibit [redacted] attached, show a distribution ratio of [redacted].

Response to question 3.

The use of the [redacted] is not new to drug delivery. Most [redacted] [redacted]. The extensive history of this [redacted]. See response to [redacted] under the [redacted] section above for further information.



Re: K991543

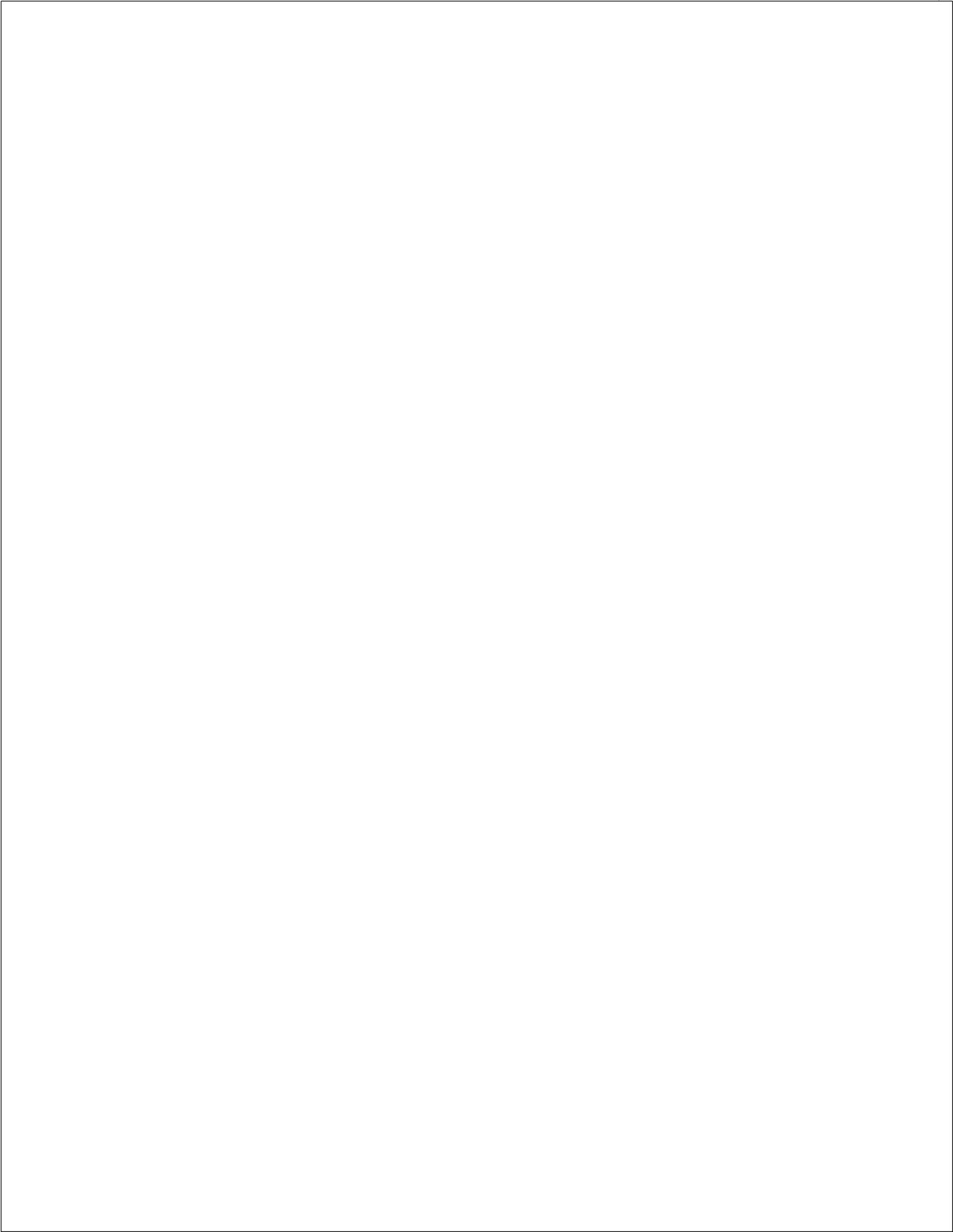
We believe that the above-enumerated responses answer your questions. Please consider the changes listed in your continued review of this 510(k).

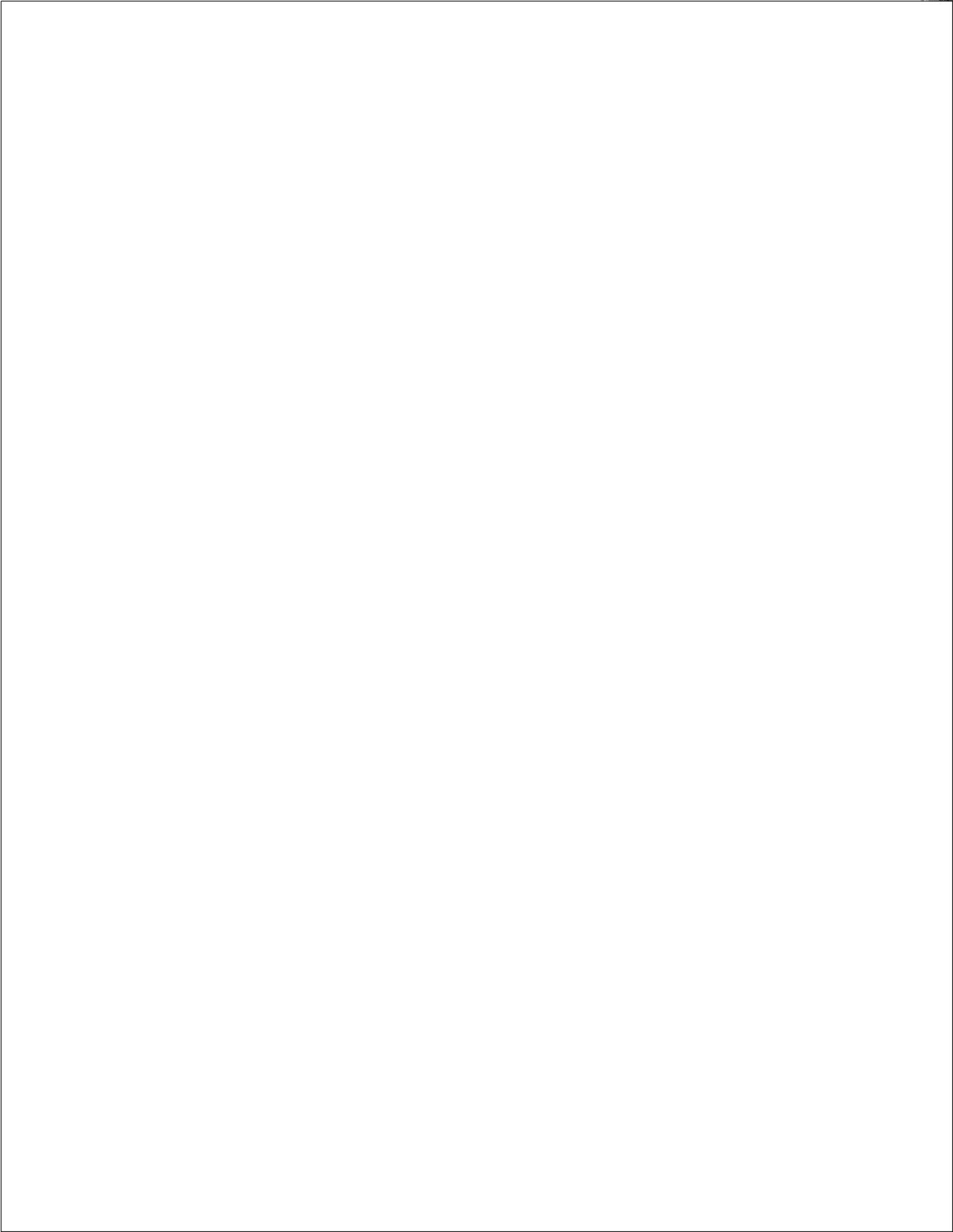
If you have any further questions, please call me for an expedited response.

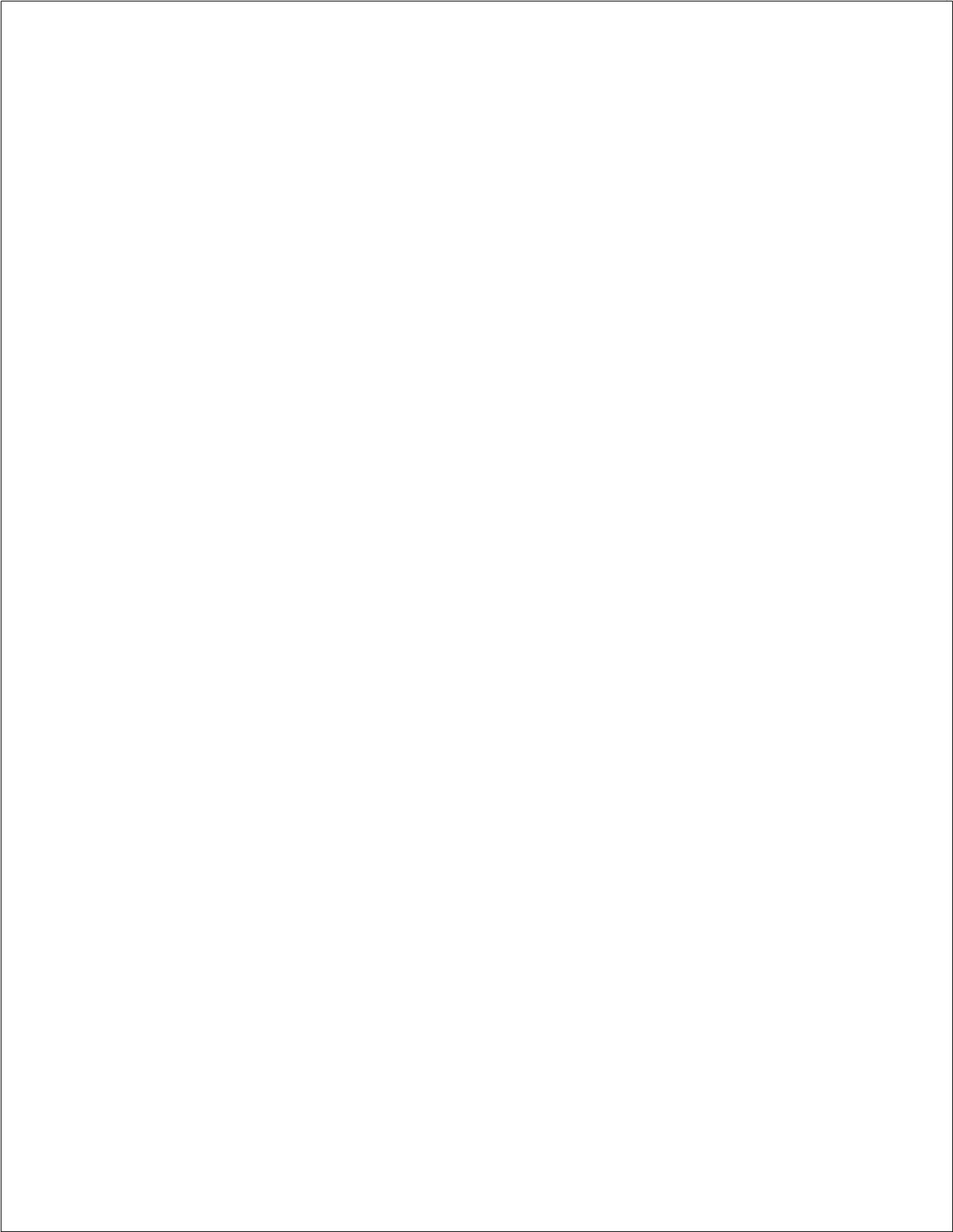
Sincerely,

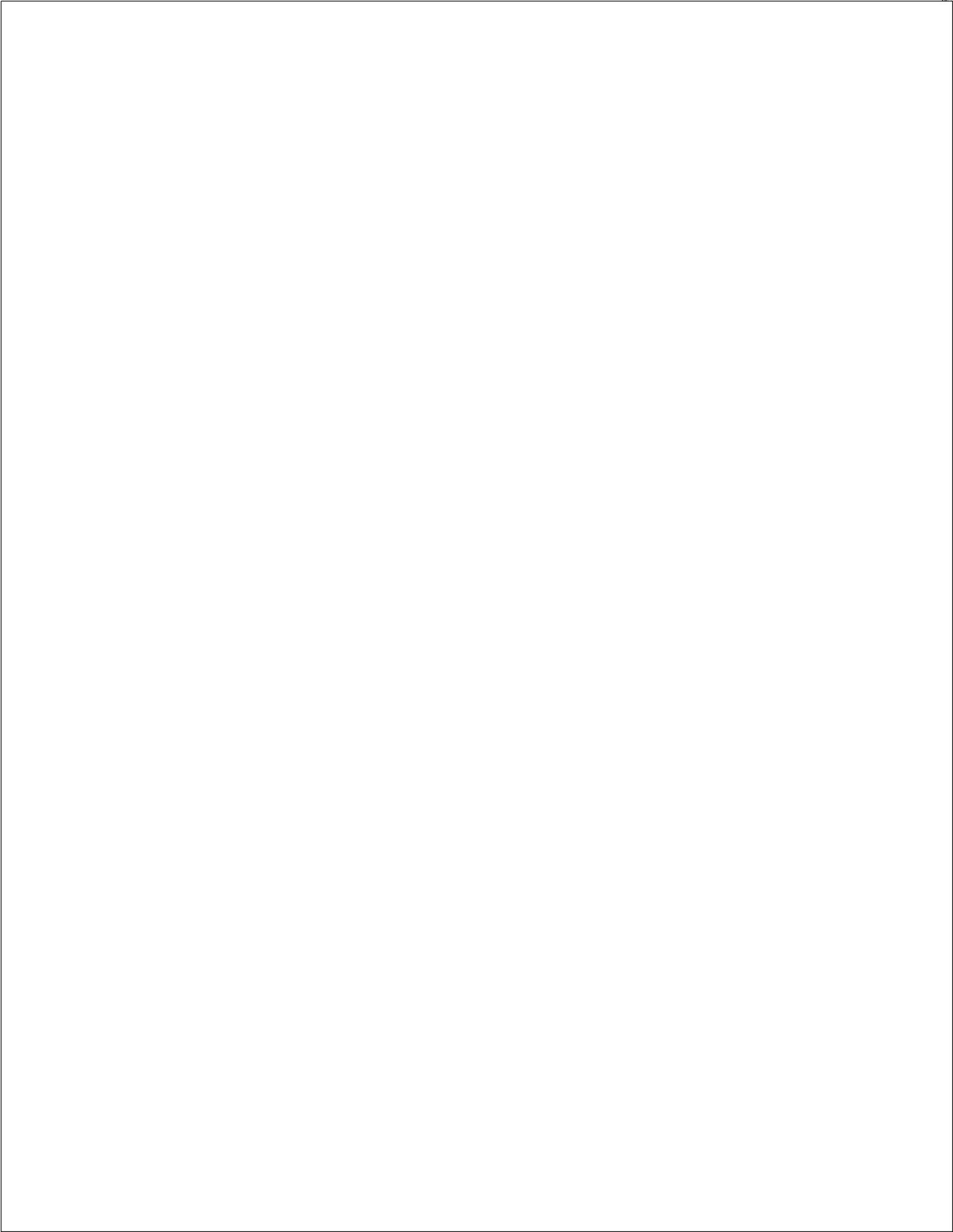
A handwritten signature in black ink, appearing to read "Stanley E. Fry", written over the word "Sincerely,".

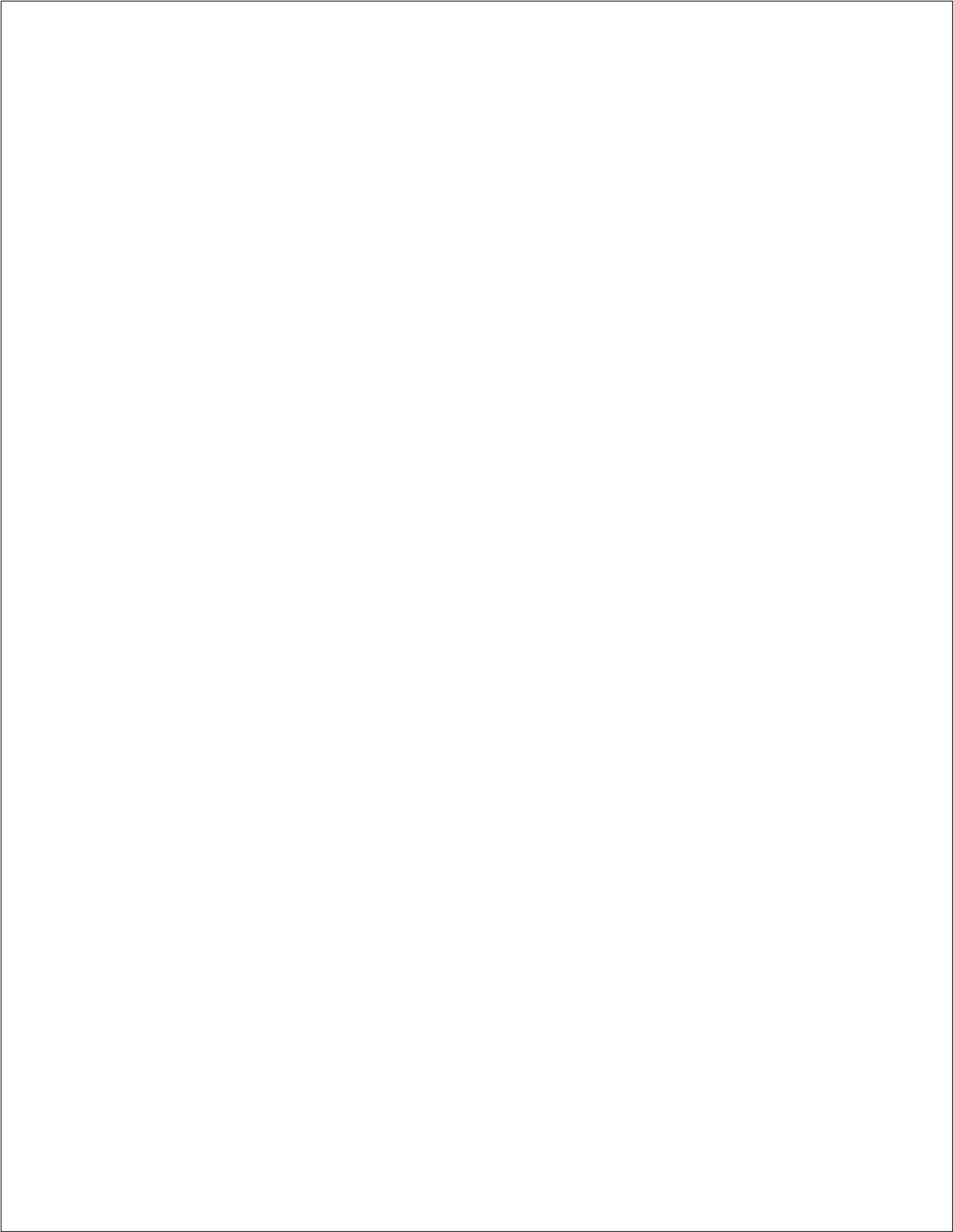
Stanley E. Fry
Vice President,
Regulatory Affairs/
Quality Assurance













DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 1999

Robert J. Bard, Esq. R.A.C.
Vice President, Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K991543
Intra Op Catheter
Dated: April 30, 1999
Received: May 3, 1999

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

1. Please provide the values for the following mechanical and performance parameters derived from the testing of your final sterilized device. Please also describe all pre-testing (a.k.a. pre-conditioning or conditioning) testing conditions in full detail.¹ We need performance and mechanical strength data in order to determine if a device is safe and effective for its intended purpose. The requested testing is as follows:

- a) tensile strength, flexural strength, and percent elongation of the catheter tube,²

Please perform the following tests when applicable -

- b) the security of attachment between the and the AND/OR

the amount of torque necessary to remove the connector from the catheter tube,

[Note: Security of attachment can be equated with strength of union.]

- c) leakage at the hub, and
- d) the catheter burst pressure (positive).

JB

Note: The number of test specimens/samples to be tested should be around 30. If you test a smaller number, you must provide a clear justification, both scientific and statistical, that the results for the smaller sample size supports a decision that your device is safe and effective for its intended use.

¹ The description of general test conditions should include: (a) any mention of pre-conditioning prior to the tests, including the temperature and humidity at which the specimens were maintained, the length of time they were maintained, and other environmental factors to which they were exposed (e.g., sunlight, ionizing radiation, non-ionizing radiation); (b) the testing protocol including the manner in which the specimens were prepared for the tests (e.g., part of device chosen for the specimen, length of specimen) and a step-by-step testing procedure; (c) the environmental conditions during the tests (temperature, humidity, etc.); and (d) a description of the test equipment including name, manufacturer, model number, and the most recent date the equipment was calibrated. [Much of the above would be satisfied by referencing an industry standard if such standard was followed.]

² This testing should be performed on the [redacted] section of the tube, the distal end near the tip which is [redacted] This is particularly significant, since the [redacted] of the catheter is composed of the [redacted]

[redacted] The reason is that the [redacted] give rise to [redacted] their locations which means that [redacted]

2. Please explain the effect that damage to [redacted] will have on the safety and effectiveness of the catheter. Please also explain the manner in which you intend to determine [redacted] since the [redacted] of the catheter wall may not exhibit simultaneous failure.
3. Please revise your Indications for Use by removing the sentence, "Routes of administration may be either, intraoperative, intramuscular, subcutaneous, or percutaneous."

4. Please explain the term [redacted], a term you used to describe the [redacted] of which your catheter is [redacted]
5. Please provide us with a sample of your device which contains kit components and both types of catheters, one with [redacted] and one with [redacted].

Regarding Anesthesia Infusion

1. Please clarify the pressure/flow characteristics of your catheter as compared to the specifications required for use with the specific pump (performance data).
2. Please specify the actual distribution of fluid administration along the catheter. Please indicate if specifications exist which assure even distribution of the fluid along the catheter and, if so, please provide said specifications along with performance data which verifies that your catheter meets such specifications.
3. Please provide valid, scientific data that your [redacted]

[redacted] In particular, please indicate as to whether there is any [redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(1), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed

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Page 4 - Mr. Bard

as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mr. William M. Burdick at (301) 594-1287. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely,



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

26

Robert J. Bard, Esq. R.A.C.
Vice President, Regulatory and Legal Affairs
I-Flow Corporation
20202 Window Drive
Lake Forest, California 92630

Re: K991543
Intra Op Catheter
Dated: April 30, 1999
Received: May 3, 1999

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following:

1. Please provide the values for the following mechanical and performance parameters derived from the testing of your final sterilized device. Please also describe all pre-testing (a.k.a. pre-conditioning or conditioning) testing conditions in full detail.¹ We need performance and mechanical strength data in order to determine if a device is safe and effective for its intended purpose. The requested testing is as follows:

- a) tensile strength, flexural strength, and percent elongation of the catheter tube,²

Please perform the following tests when applicable -

- b) the security of attachment between the and the AND/OR

the amount of torque necessary to remove the connector from the catheter tube,

[Note: Security of attachment can be equated with strength of union.]

- c) leakage at the hub, and
- d) the catheter burst pressure (positive).

21

Note: The number of test specimens/samples to be tested should be around 30. If you test a smaller number, you must provide a clear justification, both scientific and statistical, that the results for the smaller sample size supports a decision that your device is safe and effective for its intended use.

¹ The description of general test conditions should include: (a) any mention of pre-conditioning prior to the tests, including the temperature and humidity at which the specimens were maintained, the length of time they were maintained, and other environmental factors to which they were exposed (e.g., sunlight, ionizing radiation, non-ionizing radiation); (b) the testing protocol including the manner in which the specimens were prepared for the tests (e.g., part of device chosen for the specimen, length of specimen) and a step-by-step testing procedure; (c) the environmental conditions during the tests (temperature, humidity, etc.); and (d) a description of the test equipment including name, manufacturer, model number, and the most recent date the equipment was calibrated. [Much of the above would be satisfied by referencing an industry standard if such standard was followed.]

² This testing should be performed on the [redacted] section of the tube, the distal end near the tip which is [redacted]. This is particularly significant, since the [redacted] [redacted] The reason is that the [redacted] give rise to [redacted] their locations which means that they [redacted]

2. Please explain the effect that damage to the [redacted] [redacted] will have on the safety and effectiveness of the catheter. Please also explain the manner in which you intend to determine [redacted] since the [redacted] of the catheter wall may not exhibit simultaneous failure.

3. Please revise your Indications for Use by removing the sentence, "Routes of administration may be either, intraoperative, intramuscular, subcutaneous, or percutaneous."

4. Please explain the term [redacted] a term you used to describe the [redacted] of which your catheter is [redacted]
5. Please provide us with a sample of your device which contains kit components and both types of catheters, one with [redacted] and one with [redacted]

Regarding Anesthesia Infusion

1. Please clarify the pressure/flow characteristics of your catheter as compared to the specifications required for use with the specific pump (performance data).
2. Please specify the actual distribution of fluid administration along the catheter. Please indicate if specifications exist which assure even distribution of the fluid along the catheter and, if so, please provide said specifications along with performance data which verifies that your catheter meets such specifications.
3. Please provide valid, scientific data that your [redacted]

[redacted] In particular, please indicate as to whether there is any [redacted] and whether the [redacted]

We believe that this information is necessary for us to determine whether or not this device is substantially equivalent to a legally marketed predicate device with regard to its safety and effectiveness.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(1), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed

29

Page 4 - Mr. Bard

as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Document Mail Center (HFZ-401)
 9200 Corporate Boulevard
 Rockville, Maryland 20850

If you have any questions concerning the contents of this letter, please contact Mr. William M. Burdick at (301) 594-1287. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely,

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

**FILE
 COPY**

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
2480	BURDICK	7/23/99						
430	Cucenda	1/23/99						

30

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-480 Division
D.O.
F/t:HFZ-480:WMB:RMD:7/23/99

From: Reviewer(s) - Name(s) William M. Burdick

Subject: 510(k) Number K991543

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

- Refused to accept.
- Requires additional information (other than refuse to accept). AI Letter
- Accepted for review _____.
- 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 YES NO

This 510(k) contains:

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

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices N/A

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

Material of Biological Origin 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): _____

Review: Patricia Osende
(Branch Chief)

617DB
(Branch Code)

7/23/99
(Date)

Final Review: _____
(Division Director) (Date)

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MEMORANDUM TO THE RECORD

DATE: June 22, 1999

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850

SUBJECT: 510K Number K991543 - Intra Op Catheter

The device which is the subject of this 510(k) is a catheter kit. The single-use, nonpyrogenic, sterilized [redacted], [redacted] catheter will be marketed either as a separate catheter and connector (e.g., [redacted] is an example of an acceptable connector) or as a catheter with [redacted]. Besides the possible catheter connector, the kit may contain a "T" Peel over-the-needle catheter introducer (18 ga. X 2½ - 3½ inches). Comparable predicate devices include the SideKick Infusion Kit (K990425) and The PainBuster (K980558), both from I-Flow Corporation.

The basic form of the Intra Op Catheter [redacted] [redacted] which is fabricated from a [redacted] This [redacted] catheter is [redacted] by I-Flow with [redacted] [redacted] and multiple side-holes are [redacted] arranged along the [redacted] surface. The [redacted] the anesthetic drug to be distributed along the full length of holes rather than just the first few holes. The 20 ga. catheter is to be marketed as four models, the sole difference between models being the length (cm.): 52.5, 55, 57.5, and 60. [redacted] [redacted] which differ with each model: 2.5 cm., 5 cm., 7 cm., and 10 cm.

As mentioned above, the kits will be sterilized [redacted] to a SAL of 10⁻⁶. Validation of the sterilization cycle will be according [redacted]

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 the epidural space. The route of administration will only be surgical sites where the catheter may be positioned alongside a muscle or nerve. (Please refer to telephone memo dated June 14, 1999.) Since anesthetics will be administered, I requested a consult ("REQUEST FOR CONSULTING REVIEW" dated June 21, 1999) from the Respiratory Branch of DCRND to ascertain the types of testing and other information needed to assess the safety and effectiveness of the catheter for the delivery of anesthetics.

Questions and needed clarification raised during my review as well as Respiratory's (Michael Bazaral, MD, Ph.D.) review will be incorporated into a K-3 (Additional Information) letter which will be sent to I-Flow Corporation.

William M. Burdick
William M. Burdick
Biomedical Engineer *WPC*

cc. K991543
CHRON file

Re: K991543 I-Flow Intraop Anesthesia Conduction Catheter

Memo Date: 09 Jul 99

Clinical Review:

The device is a multi-orifice catheter intended for administration of local anesthetics or narcotics to wound sites and nerve trunks outside the epidural space. Duration of use is not specified and is presumably not limited to 72 hours. The catheter is similar to an epidural catheter, but [redacted]
[redacted]
along the perforated areas of the catheter. [redacted]

- 1) "The safety and effectiveness of this catheter for the infusion of anesthetics needs to be assessed."

There are two inherent questions:

- a) Is the instillation of anesthetic drugs into the wound or other site consistent with the labeling safe and effective in general?

Response: This apparently has already been decided (K990425 and other predicates for the general intended use of infusion of anesthetic drugs). I am not aware of specific problems that would cause re-review of the intended use.

- b) Is this specific catheter safety and effective?

Response: that is usually evaluated by assessment of biocompatibility and sterilization for safety. Some biocompatibility information is in the file; and can be reviewed.

For effectiveness there appear to be several questions not addressed in the file.

- 1) What is the pressure/flow characteristic of the catheter, compared to the specifications required for use with this specific pump (performance data).

This is mentioned in section 3.4 (page 3) but no data is provided.

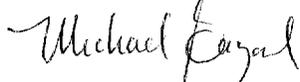
2) What is the actual distribution of fluid administration along the catheter - are there specifications for the assertion of even distribution of fluid along the catheter, and is there performance data to show that specifications are met?

3) Is the new characteristic [redacted] compatible with the anesthetic drugs? [redacted]

[redacted]
Anesthetic drugs do not react with most plastics, and [redacted]

[redacted]
compatibility with the drugs is [redacted]

There is no special information that ADDG has on these subjects, so it would be reasonable to ask the manufacturer about these topics. I think there is no need for additional ADDG review. If there are unresolved questions related to drugs, it might be necessary to ask CDER.



Michael Bazaral M.D., Ph.D.
Medical Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Avenue
Rockville, MD 20850

REQUEST FOR CONSULTING REVIEW

Date: June 21, 1999

From: William M. Burdick, Biomedical Engineer, CDRH/ODE/DDIGD/GHDB (HFZ-480)

Thru: Patricia Cricenti, Branch Chief, General Hospital Devices Branch, CDRH/ODE/DDIGD/GHDB (HFZ-480)

To: Respiratory Branch, CDRH/ODE/DCRND (HFZ-450)

PMA/IDE/510(k)#: K991543

Device Name: IntraOp Catheter

Sponsor Name: I-Flow Corporation

REASON FOR REQUEST

- New Submission Response to Deficiency Letter
- Protocol Change Design Change
- New Material(s) Labeling
- Indication(s)
- Other: _____

TYPE OF REVIEW REQUESTED

- Engineering Materials
- Sterility Toxicology
- Clinical Statistical
- Labeling Regulatory Status Determination
- Jurisdiction Determination
- Other: This catheter is to be placed in a surgical site to deliver anesthetics as well as other types of "narcotics". The safety and effectiveness of this catheter as a conduit for the infusion of anesthetics needs to be assessed.

COMMENTS:

Please Respond By: July 17, 1999

Signature of Requester: William M. Burdick

MEMORANDUM OF TELEPHONE CONVERSATION

DATE: June 14, 1999

TO: Robert J. Bard
Vice President
Regulatory & Legal Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Tel.: (949)206-2700
Fax: (949)206-2603

FROM: William M. Burdick
HHS/PHS/FDA/ODE/DDIGD/GHDB
HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850
Tel.: (301)594-1287
Fax: (301)594-2358

SUBJECT: 510K Number K991543 - Intra Op Catheter by I-Flow Corporation

I called Mr. Bard to clarify the intended use and the Indications for Use. The Indications for Use form stated that the catheter could be used for the infusion of anesthesia and other "narcotics". Routes of administration appeared to include nerve trunks outside the epidural space, and a somewhat vague reference to percutaneous, subcutaneous, and intramuscular. Mr. Bard explained that the catheters were only to be used at surgical sites, and that references to, for example, intramuscular routes were meant to convey the fact that the catheter may lay on top of a muscle, etc.

I asked Mr. Bard if the predicates he submitted were cleared for such uses, and he stated that they were epidural catheters and, therefore, not cleared for such uses. Then, I asked if there were any predicates. He replied that Ms. Irene Naveau had worked on some kits which included such catheters.

William M. Burdick
William M. Burdick
Biomedical Engineer

cc. K991543
CHRON file

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: <u>Intraop Catheter</u>					K 991543			
Submitter (Company): <u>I-Flow Corporation</u>								
Items which should be included (circle missing & needed information)	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING	
	YES	NO	YES	NO	YES	NO		
1. Cover Letter clearly identifies Submission as:								
a) "Special 510(k): Device Modification"							GO TO # 2,3	
b) "Abbreviated 510(k)"							GO TO # 2,4,5	
c) Traditional 510(k)							GO TO # 2,4,5	
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED	
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)		NA		YES		NO		AND IS MISSING
		SPECIALS		ABBREVIATED		TRADITIONAL		
YES	NO	YES	NO	YES	NO			
a) trade name, classification name, establishment registration number, device class						✓		
b) OR a statement that the device is not yet classified		FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device		NA				✓		
d) compliance with Section 514 - performance standards		NA				N/A		
e) address of manufacturer						✓		
f) Truthful and Accurate Statement						✓		
g) Indications for Use enclosure						✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)						✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)						N/A		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals						✓		
k) Proposed Labeling:						✓		
i) package labeling (user info)						✓		
ii) statement of intended use						✓		
iii) advertisements or promotional materials						✓		
i) MRI compatibility (if claimed)						✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						✓		
i) Labeling						✓		
ii) intended use						✓		
iii) physical characteristics						✓		
iv) anatomical sites of use						✓		
v) performance (bench, animal, clinical) testing		NA				✓		
vi) safety characteristics		NA				✓		
m) If kit, kit certification						✓		
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE								
a) Name & 510(k) number of legally marketed (unmodified) predicate device								
b) STATEMENT - INTENDED USE AND INDICATIONS FOR								
							* If no - STOP not a special	

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
d) Design Control Activities Summary				
i) 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				
ii) 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				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) 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				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) 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							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below			
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed			
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device			
v) A specification of any deviations from each applicable standard that were applied			
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference			
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations			
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards			

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							✓
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							✓
i) sterilization method							✓
ii) SAL							✓
iii) packaging							✓
iv) specify pyrogen free							✓
v) _____							
vi) _____							
c) Software validation & verification:							N/A
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: 5/10/99

Reviewer: Senor & Smallwood
 Concurrence by Review Branch: _____

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

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1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A

Type of Submission

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1

Reason for Submission — 510(k)s Only

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> New device | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

Section B2

Reason for Submission — PMAs Only

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Request for applicant hold | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request to remove or add manufacturing site | |
| <input type="checkbox"/> Other reason (specify): | | |

Section B3

Reason for Submission — IDEs Only

- | | | |
|---|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol- other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

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FDA Document Number:

Section C

Product Classification

Product code: 73 BSO

C.F.R. Section: 868.5120

Device class:

- Class I Class II
 Class III Unclassified

Classification panel: Anesthesiology

Section D

Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 73 BSO	2 73 CAZ	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:

- 510(k) summary attached
 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K840202	1 Epidural Catheter	1 TFX Medical (Aries Med)
2 K813186	2 Perifix Set	2 B Braun Medical
3 K981329	3 FETH-R-KATH	3 Epimed International
4	4	4
5	5	5
6	8	8

Section E

Product Information — Applicable to All Applications

Common or usual name or classification name: Anesthesia Conduction Catheter

Trade or proprietary or model name	Model number
1 IntraOp Catheter	1
2	2
3	3
4	4
5	5
6	6

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: Laboratory testing Animal trials Human trials

Indications (from labeling): The IntraOp 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

46

FDA Document Number:

Section F Manufacturing / Packaging / Sterilization Sites

<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: I-Flow Corporation

Division name (if applicable):	Phone number (include area code): (949) 206-2700 ext. 2670
--------------------------------	---

Street address: 20202 Windrow Drive	FAX number (include area code): (949) 206-2603
-------------------------------------	---

City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630
-------------------	----------------------	-----------------	--------------------------

Contact name: Robert J. Bard, Esq., R.A.C.

Contact title: Vice President of Regulatory and Legal Affairs

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
---	--	---	---

Company / Institution name:

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

Street address:	FAX number (include area code): ()
-----------------	--

City:	State / Province:	Country:	ZIP / Postal Code:
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Contact name:

Contact title:

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
---	--	---	---

Company / Institution name:

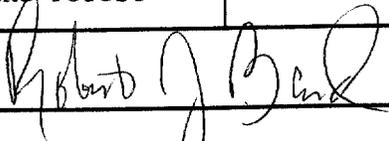
Division name (if applicable):	Phone number (include area code): ()
--------------------------------	--

Street address:	FAX number (include area code): ()
-----------------	--

City:	State / Province:	Country:	ZIP / Postal Code:
-------	-------------------	----------	--------------------

Contact name:

Contact title:

				FDA Document Number:
Section G Applicant or Sponsor				
Company / Institution name: I-Flow Corporation			FDA establishment registration number: 2026095	
Division name (if applicable):			Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive			FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630	
Signature: 				
Name: Robert J. Bard, Esq., R.A.C.				
Title: Vice President of Regulatory and Legal Affairs				
Section H Submission correspondent (if different from above)				
Company / Institution name:				
Division name (if applicable):			Phone number (include area code): ()	
Street address:			FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:	
Contact name:				
Contact title:				

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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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

May 04, 1999

I-FLOW CORP.
20202 WINDROW DR.
LAKE FOREST, CA 92630
ATTN: ROBERT J. BARD

510(k) Number: K991543
Received: 03-MAY-1999
Product: INTRAOP 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.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. 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 Assistance (DSMA) 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 (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. 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 DSMA 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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K991543



I-FLOW CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(800) 448-3569 (949) 206-2700
Fax (949) 206-2600

Premarket Notification - 510(k)

Via Federal Express
April 30, 1999

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

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 *Intra Op Catheter* prior to the introduction into interstate commerce for commercial distribution.

The *Intra Op Catheter* is substantially equivalent the B. Braun Epidural Catheter, the TFX Catheter and the Epimed International FETH-R_KATH catheter .

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

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

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Telephone: 949.206.2700
Fax: 949.206.2600

Sincerely,

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

RECEIVED

MAY 3 2 01 PM '99

FDA/CDRH/ODE/DMC

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PS

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II



I-FLOW
CORPORATION

20202 Windrow Drive
Lake Forest, CA 92630
(500) 448-3569 (949) 206-2700
Fax (949) 206-2600

Premarket Notification - 510(k)

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Vice President Regulatory and Legal Affairs

I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630
Telephone: 949.206.2700
Fax: 949.206.2600

Sincerely,

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

RECEIVED
MAY 3 2 01 PM '99
FDA/CDRH/ODE/DMC

15

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission:

FDA Document Number:

Section A Type of Submission

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1 Reason for Submission — 510(k)s Only

- New device
- Additional or expanded indications
- Change in technology, design, materials, or manufacturing process
- Other reason (specify):

Section B2 Reason for Submission — PMAs Only

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request to remove or add manufacturing site | |

Section B3 Reason for Submission — IDEs Only

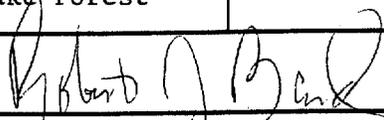
- | | | |
|---|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol - other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

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				FDA Document Number:	
Section C Product Classification					
Product code: 73 BSO		C.F.R. Section: 868.5120		Device class:	
Classification panel: Anesthesiology				<input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Section D 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 73 BSO	2 73 CAZ	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 K840202	1 Epidural Catheter			1 TFX Medical (Aries Med)	
2 K813186	2 Perifix Set			2 B Braun Medical	
3 K981329	3 FETH-R-KATH			3 Epimed International	
4	4			4	
5	5			5	
6	8			8	
Section E Product Information — Applicable to All Applications					
Common or usual name or classification name: Anesthesia Conduction Catheter					
Trade or proprietary or model name				Model number	
1 IntraOp Catheter				1	
2				2	
3				3	
4				4	
5				5	
6				6	
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					
Indications (from labeling): The IntraOp 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					

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		FDA Document Number:	
Section F: Manufacturing / Packaging / Sterilization Sites			
<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: I-Flow Corporation			
Division name (if applicable):		Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive		FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630
Contact name: Robert J. Bard, Esq., R.A.C.			
Contact title: Vice President of Regulatory and Legal Affairs			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

				FDA Document Number:
Section G Applicant or Sponsor				
Company / Institution name: I-Flow Corporation			FDA establishment registration number: 2026095	
Division name (if applicable):			Phone number (include area code): (949) 206-2700 ext. 2670	
Street address: 20202 Windrow Drive			FAX number (include area code): (949) 206-2603	
City: Lake Forest	State / Province: CA	Country: U.S.A.	ZIP / Postal Code: 92630	
Signature: 				
Name: Robert J. Bard, Esq., R.A.C.				
Title: Vice President of Regulatory and Legal Affairs				
Section H Submission correspondent (if different from above)				
Company / Institution name:				
Division name (if applicable):			Phone number (include area code): ()	
Street address:			FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:	
Contact name:				
Contact title:				

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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 Vice President of Regulatory and Legal Affairs of I-Flow Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification for the *Intra Op Catheter* are truthful and accurate and that no material fact has been omitted.



Signature

Robert J Bard, Vice President of Regulatory and Legal Affairs

Name

Title

I-Flow Corporation

April 30, 1999

Company

Dated

K991543

Premarket Notification - 510(k) Number

54

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)

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TABLE OF CONTENTS

1.0	GENERAL INFORMATION	Page 1
2.0	PHYSICAL SPECIFICATIONS AND DESCRIPTION.....	Page 1
3.0	OPERATIONS SPECIFICATIONS AND DESCRIPTION	Page 3
4.0	BIOLOGICAL SPECIFICATIONS.....	Page 3
5.0	CHEMICAL AND DRUG SPECIFICATIONS	Page 4
6.0	INTENDED USE.....	Page 4
7.0	LABELS AND LABELING	Page 4
8.0	STANDARDS	Page 4
9.0	PACKAGING	Page 4
10.0	STERILIZATION INFORMATION.....	Page 5
12.0	COMPARISON TO LEGALLY MARKETED DEVICES	Page 5

Appendix A - Intra Op Catheter Drawings and Picture

Appendix B - Intra Op Catheter Labeling

Appendix C – Predicate Labeling

Appendix D -

Appendix E – Biological Safety Tests of

Appendix F - Summary of Safety and Effectiveness

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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 Corporation intends to market the ***Intra Op Catheter***.
- 1.1.2 Trade Name: ***Intra Op Catheter***
- 1.1.3 Common Name: Anesthetic Catheter
- 1.1.4 Classification Name: Anesthesia Conduction Catheter
- 1.1.5 Classification Panel: Anesthesiology

1.2 Statement of Equivalence

- 1.2.1 The ***Intra Op Catheter*** is substantially equivalent to the (1) Teleflex Medical (TFX) Epidural Catheter (K840202, [redacted]) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed Internation FETH-R_KATH catheter (K981329).
- 1.2.2 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*** [redacted]
Catheter [redacted]
[redacted]
- 2.1.1.1 ***Intra Op Catheter*** is manufactured by [redacted]
[redacted]
- 2.1.1.1.1 The [redacted] catheter is made of a [redacted]
- 2.1.1.2 The [redacted] catheter is modified by I-Flow with the
[redacted]
- 2.1.1.2.1 [redacted]
- 2.1.1.3 The catheter has a [redacted]
[redacted] the device.
- 2.1.1.4 The catheter will be supplied as the following lengths and gauge size:
 - 2.1.1.4.1 20g x 52.5 cm
 - 2.1.1.4.2 20g x 55 cm
 - 2.1.1.4.3 20g x 57.5 cm
 - 2.1.1.4.4 20g x 60 cm

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- 2.1.2 The catheter package may contain a "T" Peel catheter over needle [redacted] and/or a catheter connector [redacted] in addition to the catheter defined herein.
- 2.1.3 The catheter is suitable for use as an ambulatory device and is intended for use in hospitals, home environments or alternative care sites.
- 2.1.4 See Appendix A for drawings of the *Intra Op Catheter*.

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 [redacted]

2.2.1.1.2 An alternate configuration [redacted]

2.2.2 Each model consists of the following:

2.2.2.1 Catheter sizes:

2.2.2.1.1 20G x 52.5 cm

2.2.2.1.2 20G x 55 cm

2.2.2.1.3 20G x 57.5 cm

2.2.2.1.4 20G x 60 cm

2.2.2.2 Each of the four catheter sizes will be available as a separate catheter with a currently marketed catheter connector ([redacted])

2.2.2.3 A "T" peel catheter over needle [redacted] 18G X 2 1/2" - 3 1/2"

2.3 Components and Materials

2.3.1 See Appendix D for [redacted]

3.0 OPERATIONAL SPECIFICATIONS AND DESCRIPTIONS

3.1 The *Intra Op Catheter* will be used for the delivery of local anesthetics or narcotics to surgical wound sites and nerve trunks outside of the epidural space.

3.2 The catheter will be closed end having multiple sides holes. Lengths of the multiple holes will be 2.5", 5", 7" and 10". The length of holes will allow drug to be infused over a wide wound area.

3.2.1 [redacted] (2.5, 5, 7, or 10 inches).

ced

3.2.2 [redacted] allows the anesthetic drug to be distributed across the full length of holes rather than just the first few holes. (See demonstration [redacted])

- 3.3 The distal end of the catheter will be placed in the wound site prior to final closure or along a nerve using a special needle (typically known as a nerve block procedure).
 - 3.3.1 In surgical wound applications, the wound would be closed, allowing the end of the catheter to remain within the wound.
 - 3.3.2 The proximal end of the catheter may be attached to an infusion pump or it may be attached intermittently to a syringe for periodic injections of anesthetic drugs.

3.4 **Flow Rate Performance Data:** Testing occurred at standard operating conditions. Flow rate through the *Intra Op Catheter* were measured and tested against [redacted]. [redacted]. Flow rates from 0.5 to 200 ml/hr produced equal performance for the two catheters.

4.0 BIOLOGICAL SPECIFICATIONS

- 4.1 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.
- 4.2 I-Flow Corporation certifies that to the best of its knowledge that all materials are exactly the same as in legally marketed devices and the conditions of use are comparable.
- 4.3 Biological testing is in conformance with ISO 10993 Part 1 for fluid path components.
[redacted]

4.4 Based on the requirements of ISO 10993-1 and FDA G95-1 Guidelines the catheter has been tested to and passed the following tests.

- 4.4.1 [redacted]
- 4.4.2 [redacted]
- 4.4.3 [redacted]
- 4.4.4 [redacted]
- 4.4.5 [redacted]
- 4.4.6 [redacted]
- 4.4.7 [redacted]
- 4.4.8 [redacted]

4.5 The *Intra Op Catheter* is categorized as follows:

- 4.5.1 Device Category: [redacted]
- 4.5.2 Body Contact: [redacted]
- 4.5.3 Contact Duration: [redacted]

cel

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.
- 6.2 Routes of administration may be intraoperative, intramuscular, subcutaneous or percutaneous.
- 6.3 The catheter is single patient use only.

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.
- 7.2 The Directions for Use labeling:
 - 7.2.1 Provides comprehensive directions for preparation and use.
 - 7.2.2 Describes the routes of administration as it relates to intended use.
 - 7.2.3 Contains warning information.
 - 7.2.4 Contains the prescription statement required under 801.109 (b)(1).
 - 7.2.5 Includes the specifications of the *Intra Op Catheter*.
- 7.3 Packaging labels
 - 7.3.1 Contains the prescription statement required under 801.109(b)(1).
- 7.4 Appendix G contains predicate labels and labeling

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 [REDACTED]
- 9.2 Packaging is suitable for [REDACTED]
- 9.3 Package aging tests have been conducted on the [REDACTED] packaging material. The results of challenge testing have determined that the [REDACTED] pouches used to package the catheter maintains sterility in excess of [REDACTED]

u2

10.0 STERILIZATION INFORMATION

10.1 The method of sterilization is [REDACTED]

10.2 [REDACTED]

10.2.1 [REDACTED]

10.2.2 [REDACTED]

10.2.3 [REDACTED]

10.3 [REDACTED]

10.4 The *Intra Op Catheter* is labeled non-pyrogenic.

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 Intended Use

11.2.1 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.

11.2.2 (1) Teleflex Medical (TFX) Epidural Catheter (K840202, originally submitted by Aries) (2) the B. Braun Perifix Set (K813186) and (3) the Epimed International FETH-R_KATH catheter are intended to administer to a patient conduction, regional, or local anesthesia and specifically, administration of anesthetic into the epidural space.

11.3 Device Descriptions

11.3.1 Comparisons

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

11.3.1.2 All of the devices have the same or similar gauge sizes (approximately 20G).

11.3.1.3 The *Intra Op Catheter* uses the [REDACTED]

11.3.1.4 The [REDACTED] is used in the I-Flow PainBuster K980558 and K982946; Nerve Block K984502; Paragon Pain Management Kit K984146; and SideKick Pain Management kit K990425. The [REDACTED] catheter is identified in all of the name kits. (See Appendix C for I-Flow product

WB

labeling.) All of the kits has similar intended uses as ***the Intra Op Catheter***.

11.3.1.5 All the catheters provide a catheter connector device similar to a [redacted] connector or [redacted]

11.3.1.6 Flow Rate Performance Data: Flow rates through the ***Intra Op Catheter*** were measured and tested against the [redacted] catheter. Flow rates from 0.5 to 200 ml/hr produced equal performance for the two catheters. With no reduction in flow.

11.3.1.7 Tensile strength: The tensile strength of the Intra Op Catheter and [redacted] were compared. Both devices survived pull tests where a pull force of [redacted] was applied to the catheters. The [redacted]

11.3.2 Materials

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

11.3.3 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.

W4

510(k) Number (if known): K 981329

Device Name: FETH-R-KATH

Indications For Use:

The Epimed Feth-R-Kath epidural catheter is intended for administration of local anesthetics into the epidural space to provide continuous epidural or caudal anesthesia for up to 72 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Marta Kraml

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

WS

510(k) Number (if known): _____

Device Name: Soft Tip Epidural Catheter Kit

Indications For Use:

For the administration of anesthetic agents into the epidural space. B. Braun recommends that the epidural catheter be removed or replaced every 72 hours.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman for AAC
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971233

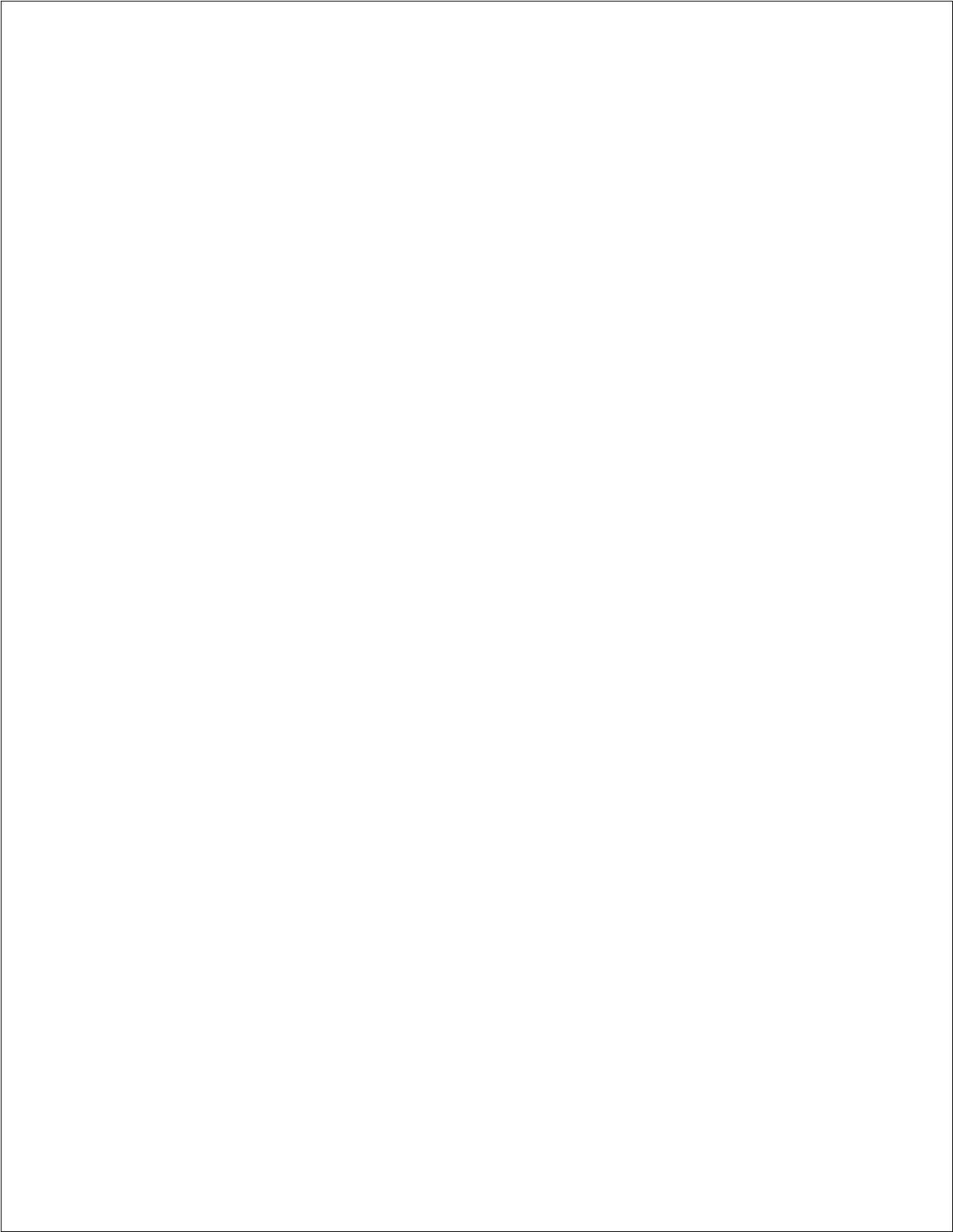
Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

lol

Appendix A – Intra Op Catheter Drawing and Picture



Appendix B – Intra Op Catheter Labeling

IntraOp Catheter

Directions for Use

Ref. Nos. IOC0205; IOC0500
IOC0705; IOC1000

INDICATIONS FOR USE

The IntraOp Catheter is designed for placement in the intraoperative site for infusing local anesthetic. For use with peel away needle or split catheter introducer. The catheter has been tested for flow rates of 0.5 ml/hr to 200 ml/hr. Flow rates outside this range may not meet performance specifications.

CAUTION

Do not use if package has been opened or is damaged or if either protector cap is not in place. The IntraOp Catheter is sterile and non-pyrogenic.

Single patient use only. Do not resterilize.

Do not withdraw catheter through needle because of the possible danger of shearing.

Use only smooth-edged atraumatic clamps or forceps.

Incompatible drug delivery may cause a precipitating reaction, which could result in an obstructed catheter.

After use, this product may be a potential biohazard. Handle and discard in accordance with accepted medical practice.

CONTRAINDICATIONS

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

Skin surface or subsurface infection at or near proposed site of insertion.

The patient is known or is suspected to be allergic to materials contained in device.

POSSIBLE COMPLICATIONS

Catheter occlusion

Catheter fragmentation

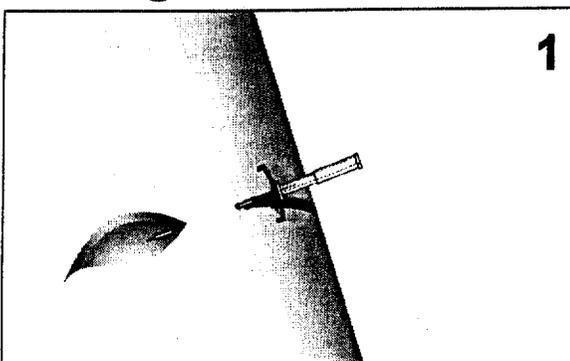
Catheter rupture

Infection/bacteremia/sepsis

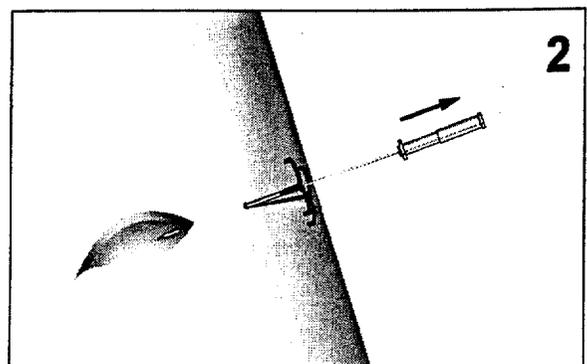
SUGGESTED CATHETER MAINTENANCE

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

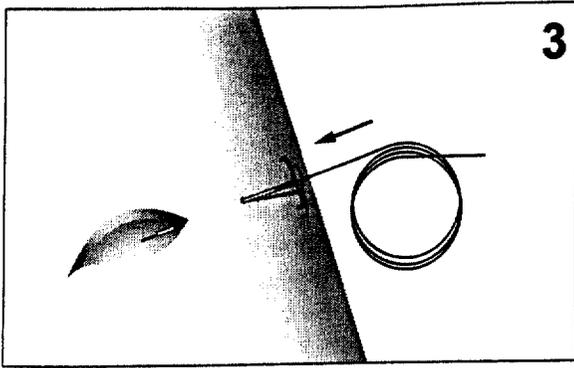
Placing the Catheter



Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site. Do not insert catheter past catheter sleeve.



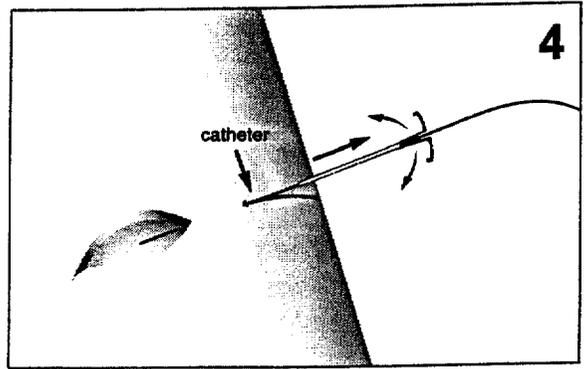
Remove the needle from the introducer.



Insert the marked end of the catheter through the hub of the introducer into the wound site to desired depth.

NOTE: Drug infusion occurs between catheter marking and marked tip.

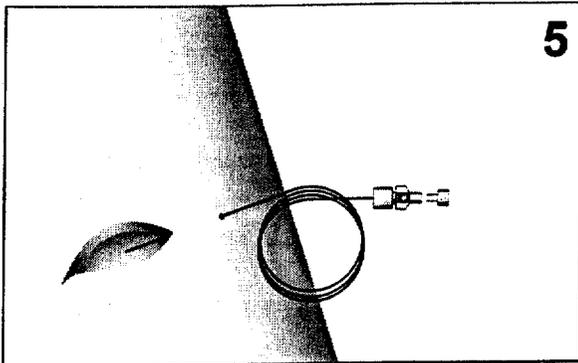
CAUTION: Assure that the catheter tip is not in a vein or artery.



While holding catheter tightly in place, slide introducer needle out and peel away from catheter. Assure catheter placement in wound site.

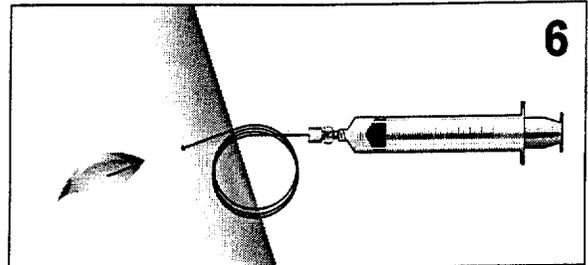
NOTE: Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement such that occlusion will not occur during use and that catheter removal will not be impeded.

Do not use excessive force to remove catheter.



Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed.

Catheter may need to be secured with tape to maintain catheter placement.



Attach syringe to catheter connector and prime catheter.

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

U.S. and Foreign Patents Pending.

For Customer Service
Call: 1.800.448.3569
949.206.2700
www.I-Flowcorp.com



European Representative:
MPS Medical Product Service GmbH
Borngasse 20, 35619 Braunfels, Germany

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LAKE FOREST, CA 92630
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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)
Closed Tip 6.35 cm (2.5 in.) Multi-Hole Distribution



STERILE



LOT

SEE DIRECTIONS FOR USE.
CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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IntraOp Catheter

20GA x 63.5 cm (25 in.)
Closed Tip 12.7 cm (5 in.) Multi-Hole Distribution



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IntraOp Catheter

20GA x 63.5 cm (25 in.)
Closed Tip 19.05 cm (7.5 in.) Multi-Hole Distribution



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I-FLOW CORPORATION, LAKE FOREST, CA U.S.A. PART NO. 400XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)
Closed Tip 25.4 cm (10 in.) Multi-Hole Distribution



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REF IOC0205

PART NO. 500XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)

Closed Tip 6.35 cm (2.5 in.) Multi-Hole Distribution



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REF IOC0500

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

PART NO. 500XXXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)

Closed Tip 12.7 cm (5 in.) Multi-Hole Distribution



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REF IOC0705

PART NO. 500XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)

Closed Tip 19.05 cm (7.5 in.) Multi-Hole Distribution



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

REF IOC0100

PART NO. 500XXXX

IntraOp Catheter

20GA x 63.5 cm (25 in.)

Closed Tip 25.4 cm (10 in.) Multi-Hole Distribution



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Appendix C – Predicate Labeling

PEEL OPEN

PERIFIX PERIFIX PERIFIX

PERIFIX® Epidural Catheter Set

PRODUCT CODE
EC20-C
333530

Contents of unopened, undamaged package are:

DISPOSABLE - Destroy after single use. Do not clean or resterilize. Store at controlled room temperature.

STERILE

CONTENTS:

- One - Marked 20 GA. x 39.3 in. (100 cm) Radiopaque Polyamide Epidural Catheter with Closed Tip and Three Lateral Sideports
- One - Catheter Threading Assist Guide
- One - Screw Cap Luer Lock Catheter Connector

B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018
Assembled and packaged in U.S.A.
Components made in U.S.A. and Germany

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

P-2880

REV. 3/95

891430 EXP 1/02

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PERIFIX® Epidural Catheter Directions

Contents of unopened, undamaged package are:

STERILE

DISPOSABLE - Destroy after single use. Do not clean or resterilize.

Store at controlled room temperature.

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DIRECTIONS: Use Aseptic Technique.

Following puncture and verification of the Epidural Space, introduce the catheter tip through the Epidural Needle using the:

(1) Threading Assist Guide. The guide will increase longitudinal stability of the catheter.



CAUTION: DO NOT WITHDRAW CATHETER THROUGH NEEDLE BECAUSE OF THE POSSIBLE DANGER OF SHEARING.

Insert catheter to desired depth. Catheter markings: 5.5 cm (1 ring), 10.5 cm (2 rings), 15.5 cm (3 rings) in 1 cm increments, 20.5 cm (4 rings). The solid wide warning mark indicates exit of catheter from needle when using the Threading Assist Guide and a PERIFIX® Epidural Needle. The catheter will exit 1 cm before

the warning mark when not using the Threading Assist Guide.

Remove needle and Threading Assist Guide over catheter while holding catheter tightly in place.



(2) Introduce distal end of catheter as far as possible in central opening of transparent screw cap of catheter connector.

(3) Tighten screw cap until catheter can no longer be withdrawn. Administer test dose. Administer anesthetic as needed.



B | BRAUN

B. Braun Medical Inc.
Bethlehem, PA 18018

A4806076

P-3080

REV. 8/95

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CONTENU / CONTENIDO: 1



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

REF NB060020
PART NO. 500XXXX

NERVE BLOCK INFUSION KIT 60 ml Vol x 2 ml/hr

CONTENTS: 1 each - 60 ml Vol, 2 ml/hr Pump
1 each - 18 Ga x 2 inch Touhy Needle
1 each - 20 Ga Epidural Catheter Set
1 each - 60 ml Syringe
1 each - Transparent Dressing
1 each - Hemostasis Valve Assembly
1 each - Hookup Wire

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

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CONTENU / CONTENIDO: 1



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

REF NB065005
PART NO. 500XXXX

NERVE BLOCK INFUSION KIT 65 ml Vol x 0.5 ml/hr

CONTENTS: 1 each - 65 ml Vol, 0.5 ml/hr Pump
1 each - 18 Ga x 2 inch Touhy Needle
1 each - 20 Ga Epidural Catheter Set
1 each - 60 ml Syringe
1 each - Transparent Dressing
1 each - Hemostasis Valve Assembly
1 each - Hookup Wire

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

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REF PG100020

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

PART NO. 5001202

PARAGON INFUSION KIT 100 ml Vol x 2 ml/hr

CONTENTS: 1 each – 100 ml Vol, 2 ml/hr Administration Set
1 each – 16GA I.V. Catheter Needle
1 each – 20GA Epidural Catheter Set
1 each – 60cc Syringe
1 each – Transparent Dressing

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

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CONTENU / CONTENIDO: 1



REF PG100040

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

PART NO. 5001203

PARAGON INFUSION KIT 100 ml Vol x 4 ml/hr

CONTENTS: 1 each – 100 ml Vol, 4 ml/hr Administration Set
1 each – 16GA I.V. Catheter Needle
1 each – 20GA Epidural Catheter Set
1 each – 60cc Syringe
1 each – Transparent Dressing

PACKAGE IS NOT STERILE.
INDIVIDUAL COMPONENTS
ARE STERILE PACKAGED.



LOT

SEE DIRECTIONS FOR USE

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL.

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Fabrique par / Fabricado por:
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1303073A

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SIDEKICK™

PAIN MANAGEMENT SYSTEM

The SideKick Pain Management System includes the SideKick Pain Management Kit and SideKick Infusion Pump. The kit is designed to work with the infusion pump, which may be sold separately.

KIT CONTENTS

- 1 each - Administration Set (package sterile)
- 1 each - 16 GA I.V. Catheter Needle (package sterile)
- 1 each - 20 GA Epidural Catheter Set (package sterile)
- 1 each - Medication Label (non-sterile)
- 1 each - Carrying Case (non-sterile)

INTENDED USE

The SideKick Pain Management System is intended to provide a continuous infusion of a local anesthetic directly into an intraoperative site for postoperative pain management. Additional routes of administration include subcutaneous, intramuscular and epidural.

DO NOT USE IF PACKAGE HAS BEEN OPENED OR IS DAMAGED OR IF EITHER PROTECTOR CAP IS NOT IN PLACE.

SIDEKICK KIT IS SINGLE PATIENT USE ONLY.

SIDEKICK INFUSION PUMP IS REUSABLE AND NON-STERILE. DO NOT STERILIZE. REFER TO CARE OF THE SIDEKICK INFUSION PUMP.

CONTRAINDICATIONS

Not for intravenous or intra-arterial drug delivery.
Not for blood, blood products, lipids or fat emulsions delivery.

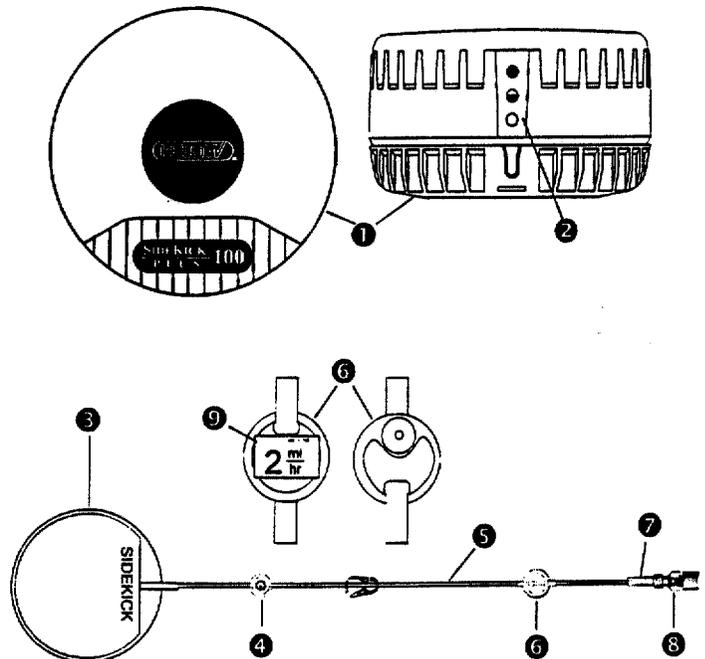
CAUTION

1. Medications used with this system should be administered in accordance with instructions provided from the drug manufacturer.
2. This product contains natural rubber latex which may cause allergic reactions. Individuals with known natural rubber latex sensitivities should not use this product.

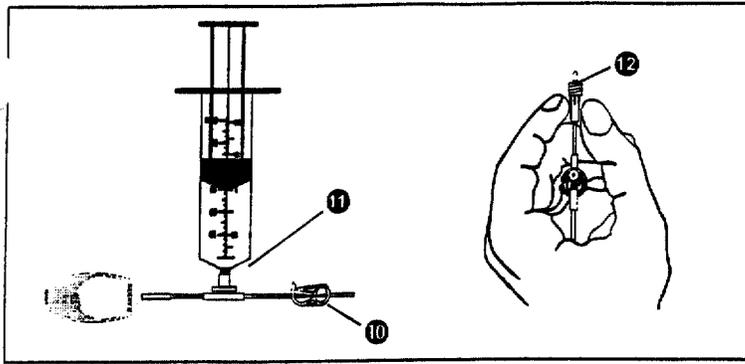
THE SIDEKICK PAIN MANAGEMENT INFUSION PUMP AND ADMINISTRATION SET

DESCRIPTION

1. SIDEKICK Infusion Pump ①
2. Fluid Level Indicator ②
3. Reservoir Bag ③
4. Fill Port ④
5. PVC Tubing (approx. 127 cm) ⑤
6. 1.2 micron air-eliminating filter ⑥
7. Flow restrictor ⑦
8. Luer Lock ⑧
9. Flow Rate Label ⑨



DIRECTIONS FOR USE



FILLING (USE ASEPTIC TECHNIQUE)

1. Close clamp on tubing. ⑩
2. Remove protective cap from fill port. Do not discard cap.
3. Attach filled syringe to the fill port and inject medication into pump. Repeat if necessary up to 100 mls. ⑪
4. Remove air from the reservoir bag by aspirating with a syringe attached to the fill port. Squeezing the sides of the reservoir bag when pulling back on the syringe will aid in removing the air.
5. Replace the cap on the fill port.
6. Label with the appropriate pharmaceutical and patient information. Do not place labels on the bag. Labels may be wrapped around the tubing.

CAUTION: SIDEKICK infusion pump, carrying case and medication label are NON-STERILE. Not to be loaded in sterile field.

PRIMING THE ADMINISTRATION SET

- Using appropriate aseptic technique, remove the cap from the Luer lock at the end of the set. Open the clamp on the tubing set and squeeze reservoir bag. The medication will flow toward the end of the Luer lock.
2. Confirm that fluid is flowing by observing the formation of a drop at the end of the Luer lock. ⑫

PLACING THE CATHETER

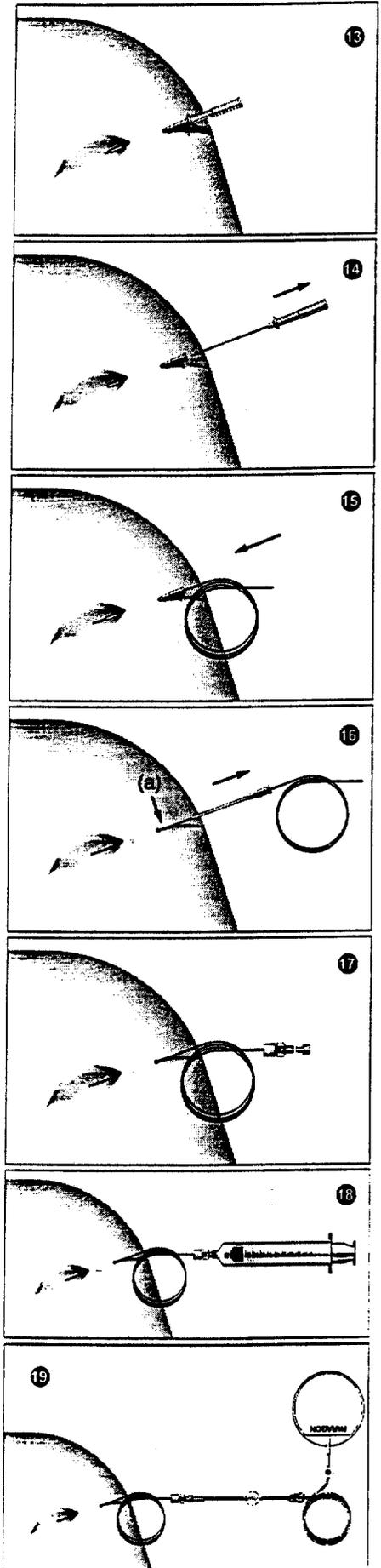
1. Insert introducer needle through the skin (approximately 3-5 cm away from wound site) then push introducer needle into the surgical wound site. ⑬
2. Remove the needle from the introducer. ⑭
3. Insert the marked end of the catheter through the hub of the introducer into the wound site (approximately 5-8 cm). ⑮

CAUTION: Assure that the catheter tip is not in a vein or artery.

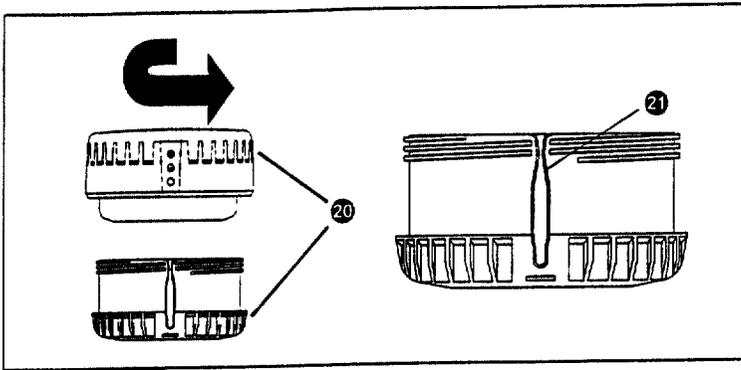
4. While holding catheter (a) tightly in place, remove introducer needle. Assure proper catheter placement in wound site. ⑯
- NOTE:** Catheter placement will vary depending on surgical procedure. Care should be taken during catheter placement such that occlusion will not occur during use and that catheter removal will not be impeded.
5. Attach the catheter connector to the unmarked end of the catheter. Tighten until catheter cannot be removed. ⑰
Catheter may need to be secured with tape to maintain catheter placement.
6. Attach syringe to catheter connector and prime catheter with local anesthetic. ⑱

WARNING: If catheter tip location cannot be verified before priming, draw back on the syringe to check for blood return. Blood return may indicate the catheter is in a vein or artery which is unsafe.

7. Attach the catheter connector to the administration set. ⑲
- Secure catheter by coiling close to insertion site and apply dressing. Secure flow restrictor to skin. (See illustration on back page.) The flow restrictor must not be in contact with cold therapy pads.



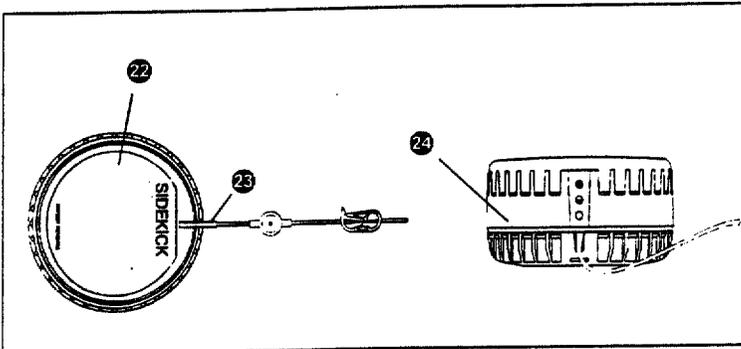
DIRECTIONS FOR USE



LOADING THE RESERVOIR BAG INTO THE SIDEKICK INFUSION PUMP

CAUTION: Infusion pump, carrying case and medication label are NON-STERILE. Not to be loaded in sterile field.

1. Twist open the top and bottom halves of the infusion pump. 20
2. Before placing the reservoir bag into the infusion pump, slide the thin portion of the administration set through the slot found on the bottom of the pump. 21
3. Center the bag in the bottom and press all around the edge of the bag to fully seat the bag in the bottom. Make sure there are no wrinkles in the bag. 22
4. Pull gently on the thick portion of the tubing so that it is fully extended and seated at the bottom of the slot. 23
5. Twist the top and bottom halves of the infusion pump together until they meet. 24

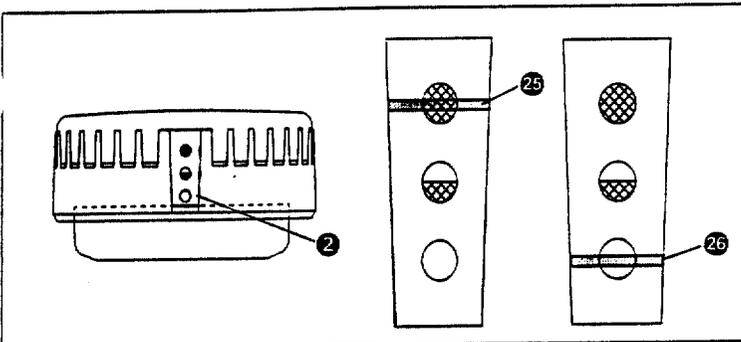


STARTING THE INFUSION

1. Start the infusion by opening the clamp on the administration set.
2. Place the infusion pump in the carrying case. The carrying case can be worn on a belt, over the shoulder, or around the waist.

THE FLUID LEVEL INDICATOR

1. The window with the markings on the side of the infusion pump is used to estimate how far the infusion has progressed. 2
2. When the reservoir bag is filled to 100 ml, the top of the pressure plate will be aligned with the top round marker. 25
3. As the infusion progresses, the plate will move to the bottom marker indicating the bag is nearly empty. 26



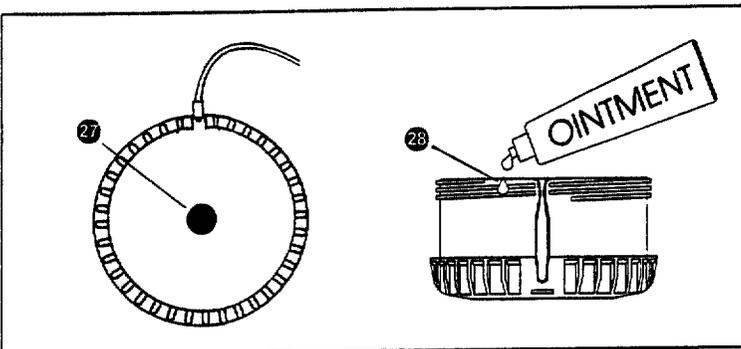
THE END OF THE INFUSION

The infusion is complete when a large blue dot appears through the bottom of the infusion pump. 27

CARE AND CLEANING OF THE SIDEKICK INFUSION PUMP

The SIDEKICK infusion pump is durable and is intended to be used for repeated drug deliveries. After each patient use, the exposed surfaces, except the threads, may be wiped clean using isopropyl alcohol or a 10% bleach solution.

NOTE: Do not submerge the infusion pump in a bleach solution. After cleaning, if the infusion pump is difficult to twist together, place a small drop of lubricating ointment (such as K-Y® Jelly) on a small section of the threads on the bottom of the infuser. Twist the top of the infuser onto the bottom to spread out the ointment. 28



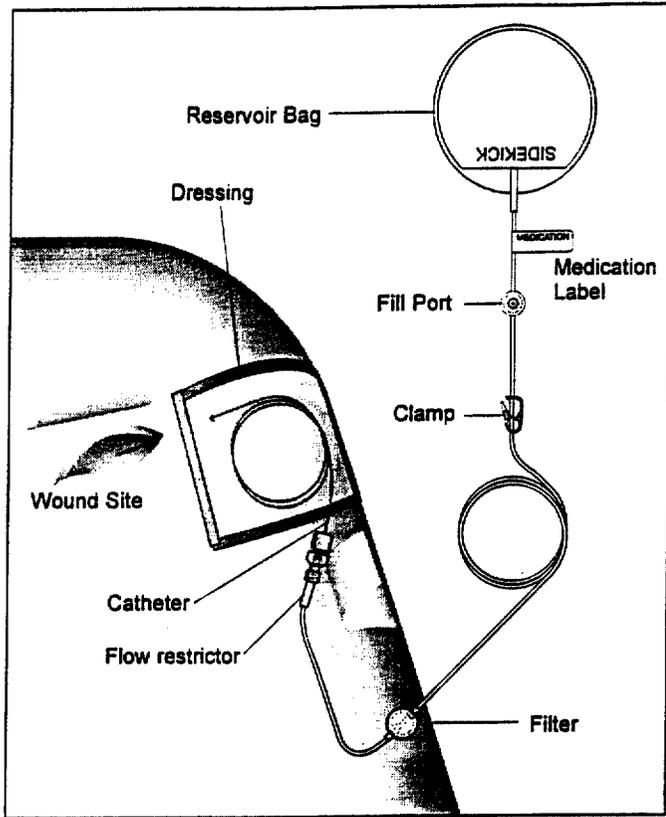
IMPORTANT

Only SIDEKICK administration sets are authorized for use with this product. I-Flow Corporation accepts no responsibility for performance, or the liability for damages, caused by the misuse of this product when used with unauthorized administration sets.

This product uses DEHP plasticized PVC. Certain solutions may be incompatible with the PVC material used in the administration set. Consult the drug package insert and other available sources of information for a more thorough understanding of possible incompatibility problems.

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DIRECTIONS FOR USE



The SIDEKICK Infusion Pump Specifications

Delivery Accuracy: $\pm 15\%$ at 95% confidence interval.

Priming volume: Allow 1 ml for loss during priming.

NOTES

- The infusion rates for each administration set are indicated on the administration set label on the filter.
- Actual infusion rates may vary from the specified range due to:
 - viscosity and/or drug concentration.
 - temperatures above or below the operating conditions.
 - the positioning of the infusion pump above or below the infusion site.
- The SIDEKICK System has been calibrated using Normal Saline as the diluent and skin contact temperature (32°C , 90°F) as the operating environment. When using Normal Saline and skin temperature the SIDEKICK System will flow at the specified nominal rate. The use of other diluents or operating temperatures other than the above will affect the nominal flow rate.

DELIVERY TIME INFORMATION FOR SIDEKICK

		100 ml Vol x 2 ml/hr pump
NOMINAL FLOW RATE (ml/hr)		2
NOMINAL VOLUME (ml)		100
MAXIMUM VOLUME (ml)		110
RETAINED VOLUME (ml)		≤ 5
APPROXIMATE DELIVERY TIME		FILL VOLUME (ml)
12 hours		25
18 hours		38
24 hours	1 day	50
48 hours	2 days	100

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a healthcare professional. Prompt removal of the catheter is advised after infusion is complete to reduce risk of infection.

For Customer Service
 Call: 1.800.448.3569
 949.206.2700
www.i-flowcorp.com

CE European Representative:
 MPS Medical Product Service GmgH
 0123 Borngasse 20, 35619 Braunfels, Germany

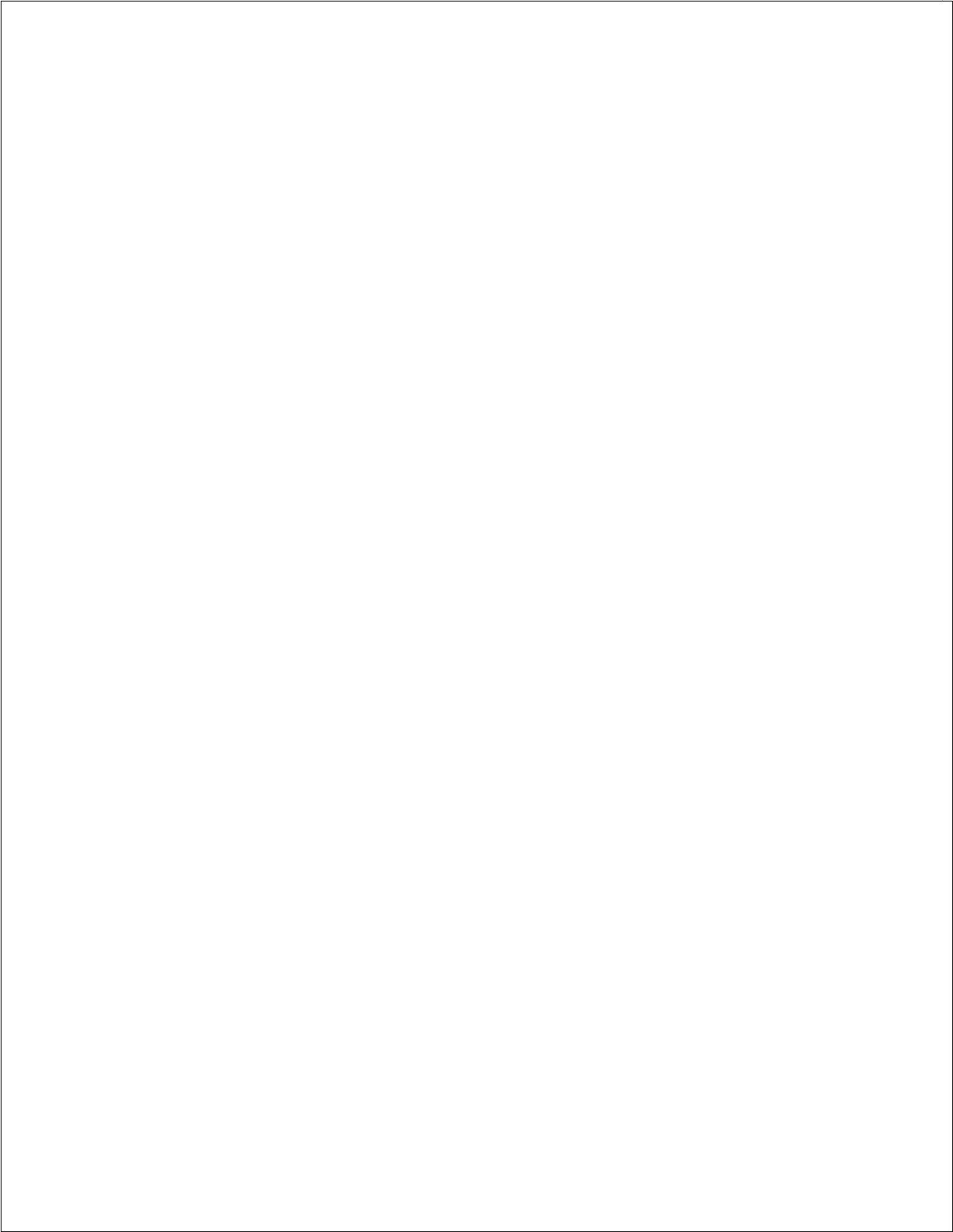
A PRODUCT OF

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

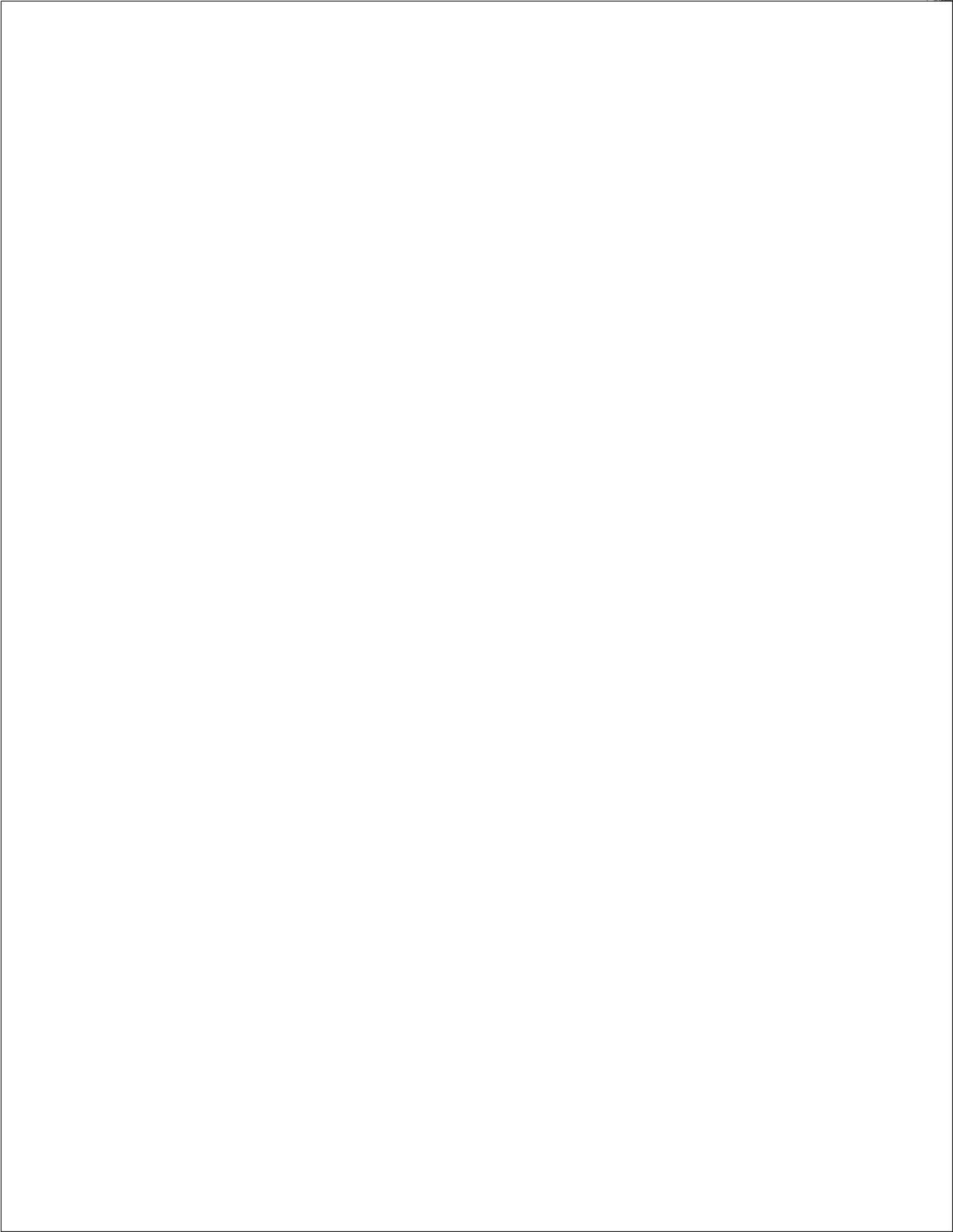
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Appendix D -



Appendix E – Biological Safety Tests



Appendix F – Summary of Safety and Effectiveness

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.

- 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.

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

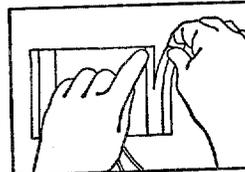
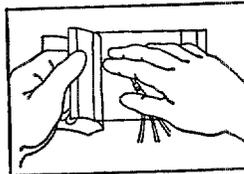
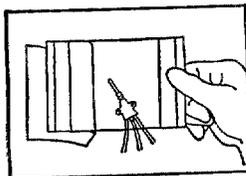
11.2.2.1 The *Intra Op Catheter's* fluid path materials are in conformance with ISO 10993 Part 1.

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.

WRAP AROUND PUMP TUBING <small>1802230A</small>	MEDICATION		
	PATIENT	_____	
	DRUG NAME	_____	
	CONC	_____ VOL	_____
DATE	_____ TIME	INITIALS _____	

Smith+Nephew

4 in x 5 in (10 cm x 13 cm) Part # 
High MVP Transparent Dressing



Single use. Sterile unless opened or damaged.

Customer Care Center: 1 800 876-1261
 Smith & Nephew, Inc., Largo, FL 33773
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OpSite **V3000** Central



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I-FLOW CORPORATION

20202 Windrow Drive

Lake Forest, CA 92630

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Re: K991543

SAMPLES

CATHETER WITH
BONDED HUB

CATHETER WITH
TOUHY BOST TYPE
CONNECTOR

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