



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (Idt)

FOLDER: K953746 - 136 pages

COMPANY: ARROW INTL., INC. (ARROW)

PRODUCT: SET, ADMINISTRATION, INTRAVASCULAR (FPA)

SUMMARY: Product: ARROW HIGH FLOW FLUID ADMINISTRATION SET
W/BLOOD FILTER & EXTENSION SE

DATE REQUESTED: Oct 8, 2014

DATE PRINTED: Oct 8, 2014

Note: Printed





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 1996

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs & Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19612

Re: K953746
Trade Name: Arrow High Flow Fluid Administration Set
W/Blood Filter and Extension Set
Regulatory Class: II
Product Code: FPA
Dated: November 30, 1995
Received: December 5, 1995

Dear Mr. Nickel:

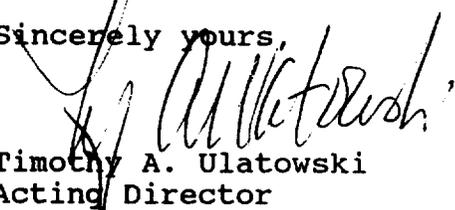
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Page 2 - Mr. Nickel

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. 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), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



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

510(K) ROUTE SLIP

510(k) NUMBER K953746 PANEL HO DIVISION DDIG BRANCH GHDB

TRADE NAME ARROW HIGH FLOW FLUID ADMINISTRATION SET W/BLOOD FILTER &

COMMON NAME _____

PRODUCT CODE _____

APPLICANT ARROW INTL., INC.

SHORT NAME ARROW

CONTACT THOMAS D NICKEL

DIVISION _____

ADDRESS 3000 BERNVILLE ROAD

READING, PA 19605

PHONE NO. (610) 478-3137

FAX NO. (____) ____-____

MANUFACTURER ARROW INTL., INC.

REGISTRATION NO. 1036844

DATE ON SUBMISSION 18-JUL-95

DATE DUE TO 510(K) STAFF 24-OCT-95

DATE RECEIVED IN ODE 10-AUG-95

DATE DECISION DUE 08-NOV-95

DECISION _____

DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
<u>S001</u>	<u>30-NOV-95</u>	<u>05-DEC-95</u>	<u>18-FEB-96</u>	<u>04-MAR-96</u>	

CORRESPONDENCE	SENT	DUE BACK
<u>C001</u>	<u>27-OCT-95</u>	<u>26-NOV-95</u> <u>HOLD LETTER</u>

Is this 510(k) identified as a Class III device _____ YES _____ NO

JURKIG

3



Memorandum

Date 1/25/96
 From REVIEWER(S) - NAME(S) Richard E. Johnson
 Subject 510(k) NUMBER K953740/S1

To THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
- Requires premarket approval. NOT substantially equivalent to marketed devices.
- Requires more data.
- 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

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

The submitter requests under 21 CFR 807.95: No Confidentiality
 Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class: 990.5440

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

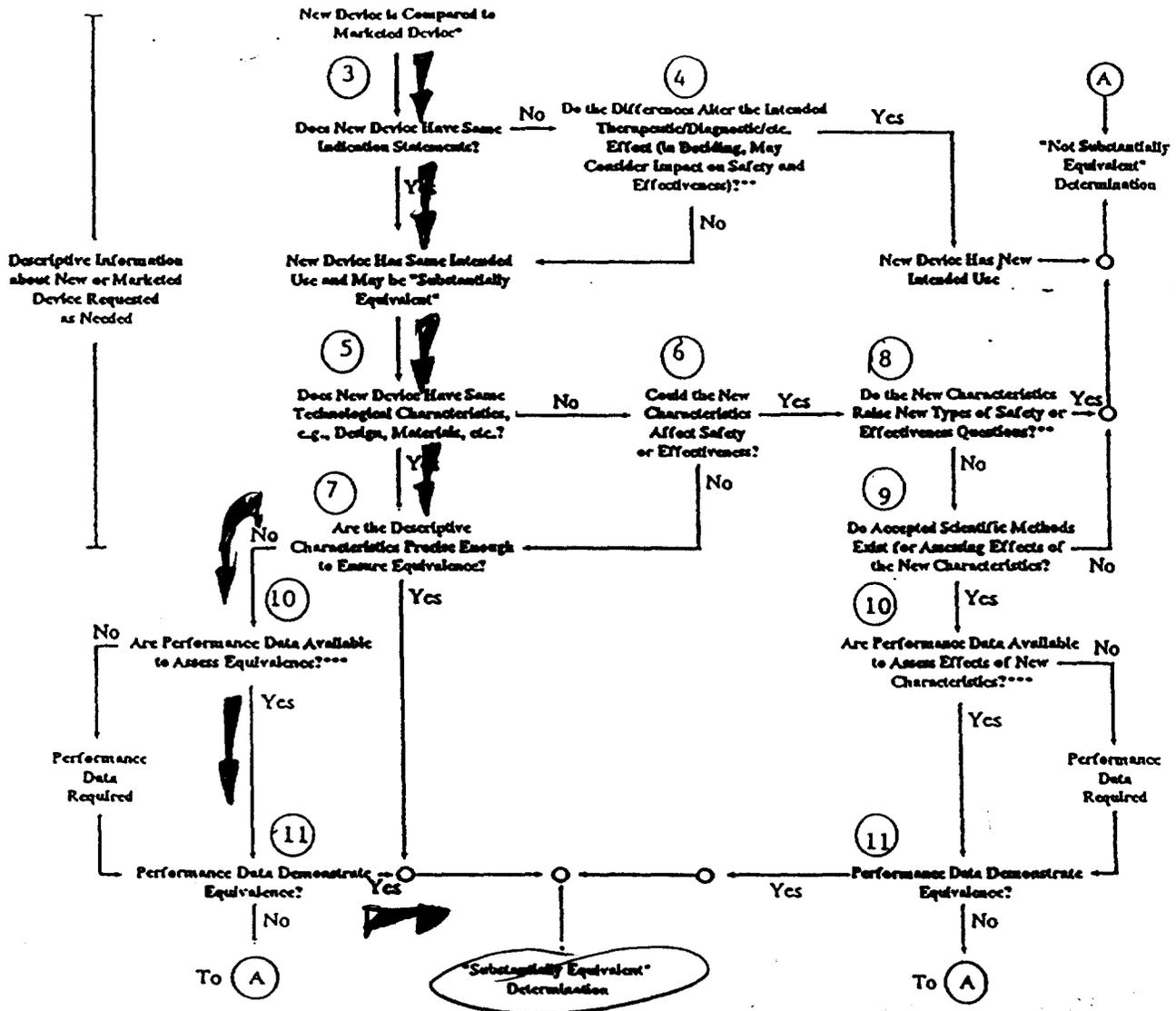
80 FPA Set, Administration, Intravascular

REVIEW: Patricia C. [Signature] 610 B 1-20-95
 (BRANCH CHIEF) (BRANCH CODE) (DATE)
 FINAL REVIEW: [Signature] 1/26/96
 (DIVISION DIRECTOR) (DATE)

Revised 3/8/95

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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-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

Premarket Notification [510(k)] Review

K953746

Date: January 25, 1996

To: The Record
From: Richard E. Galgon, Biomedical Engineer

Office: HFZ-420
Division: DDIGD/GHDB

Sponsor: Arrow International
3000 Bernville Road
Reading, PA, 19605

Contact: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
(610) 378-0131

Device Name: Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200)

I. Purpose

The referenced premarket notification represents an intention by the sponsor to introduce into interstate commerce a new medical device to be known as the Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200). This trade name and model number are identical to a similar device distributed by the sponsor since 1986.

The sponsor has sold a high flow blood and fluid administration set manufactured by Migada, Ltd, Rehovot, Isreal, since 1986. This set was purchased by the sponsor in bulk, non-sterile. The sponsor then packaged the set and sterilized it for commercial distribution. The supplier, Migada, held the 510(k) for this set, K861275.

The sponsor has found an alternate supplier who is able to provide "the exact same set." The subject 510(k) requests clearance to market this set provided by the alternate supplier.

II. Narrative Device Description

1.0 Intended Use. The Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200) is intended for high volume, rapid administration of whole blood, diluted packed cells, and physiological fluids when connected to a large bore infusion catheter.

2.0 Device Description.

Summary Information

Life-supporting or life-sustaining?	No
Implant (short-term or long-term)?	No

U

Sterile?	Yes
Single use?	Yes
Prescription use?	Yes
Home use or portable?	Yes
Drug or biologic component?	No
Kit?	No
Software-driven?	No
Electrically operated?	No
Truthful and accuracy statement?	Yes
Summary of safety and effectiveness?	No
510(k) certification?	Yes

The Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200) consists of two components, the administration set with blood filter and the extension set. The administration set from proximal to distal end consists of two vented blood spikes (acrylic, DR 100, Rohm & Haas) connected through a Y-site (PVC, MIXVIL AM/20-W17, TPV Argenta) to a drip chamber (PVC, MIXVIL AM/20-W17 and AM/88-W17, TPV Argenta) containing a 260 µm filter (polypropylene, MOPLEN S30/G, Himont). The drip chamber is attached to the administration set tubing (PVC, MIXVIL AM/14, TPV Argenta). Incorporated into the administration set tubing are two in-line luer lock T-pieces (PVC, MIXVIL AM/90-W17, TPV Argenta), and one in-line injection site. The injection site is constructed from polypropylene (NOVOLEN 1100 HX, BASF Germany), natural latex rubber (Mixture 61-FU, Farmagossa, Italy), and PVC (MIXVIL AM/90-W17, TPV Argenta). The administration set terminates in a female luer lock (MIXVIL AM/90-W17, TPV Argenta).

From proximal to distal end, the extension set consists of a rotating male luer lock (ABS, TERLURAN KR 2802TR, BASF Germany) attached to the extension tubing (PVC, MIXVIL AM/14, TPV Argenta), and terminates with a female luer lock (MIXVIL AM/90-W17, TPV Argenta). The extension set incorporates one in-line injection site identical to those used in the administration set. Both sets utilize tubing pinch clamps. Drawings for both sets are provided in Attachment 2.

2.1 Sterilization. The subject device will be sterilized to a SAL of 10^{-6} using EtO gas. The sponsor indicates EtO residual levels will be 25, 25, and 250 ppm for ethylene oxide, ethylene chlorohydrin, and ethylene glycol.

2.2 Pyrogenicity. The device will be labeled non-pyogenic. Pyrogenicity will be verified using either the LAL test or USP pyrogen test.

2.3 Packaging. The device will be unit packed in a polystyrene tray topped with a Tyvek lid.

2.4 Labeling. The sponsor has provide package labels, Instructions for Use, and promotional literature for the device. The labeling contains the prescription statement in accordance with 21 CFR §801.109(b). This device is to be changed every 24 hours. The PVC used in this device contains DEHP plasticizer.

III. Correspondence

The referenced premarket notification was received on August 10, 1995. The submission appears to have been received by the Center for Biologics Evaluation and Research (CBER) on July 21, 1995. It was then forwarded to CDRH and received as indicated.

On October 16, 1995, the sponsor was contacted via telephone. The availability of test data to support claims made in the promotional literature provided in Attachment 1 was discussed. Following, a facsimile was sent to the sponsor outlining the issues and concerns regarding this application (see telephone memorandum dated October 16, 1995).

On October 20, 1995, a facsimile in response to the telephone conversation of October 16, 1995, was received informing CDRH that the sponsor would not be able to respond to the issues raised before November 1, 1995. Therefore, they requested a hold letter be issued detailing the outstanding issues. On October 27, 1995, this application was put on hold pending the receipt of additional information and a letter was sent to the sponsor outlining the outstanding issues.

A response to the letter dated October 27, 1995, was received on December 5, 1995. The information submitted did not fully address the concerns raised in the letter dated October 27, 1995. Therefore, the sponsor was contacted on January 18, 1996 (see telephone memorandum) for additional information which had not been provided in the response.

On January 23, 1996, the sponsor provided the requested additional information. This application now contains sufficient information upon which a final decision can be made.

IV. Substantial Equivalence

The Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200) and the High Flow Administration Set cleared under K861275 have the same intended use and indications for use as well as similar technological characteristics. These devices differ only in material specification.

The geometry and components incorporated into the two devices are identical (see K861275 for dimensions of predicate device). A side-by-side comparison of the geometrical configuration and composition of these two devices is adequate to establish equivalent mechanical and functional performance between the two devices. This conclusion is confirmed by the results described in the Product Qualification Report for the subject device (Attachment 3) and those reported in the "Technical Report" for the predicate device (Attachment 2). An analysis of these results indicates both devices meet the minimum flow specification of 625 cc/min under a head height of 85 cm and 1250 cc/min at a pressure of 300 mmHg.

In order to support equivalent biocompatibility between the two devices, the sponsor has provided test protocols and results from the following tests conducted on the materials of the subject device: (1) sensitization, (2) intracutaneous reactivity, (3) cytotoxicity, (4) acute systemic toxicity, (5) hemocompatibility, and (6) mutagenicity. The results from these tests are acceptable. Therefore, the materials of the subject device are considered biocompatible for the intended use of the device per Blue Book Memorandum #G95-1.

The labeling for the subject device is comparable to current administration set labeling. Therefore, no new types of safety and effectiveness questions exist.

V. Recommendation

I believe this device is substantially equivalent to:

80 FPA Set, Administration, Intravascular

Classification should be based on:

880.5440 Class II

Richard E. Selva 1/25/96



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Document Number:

Reviewer: Richard E. Galgon

Division/Branch: Division of Dental, Infection Control, and General Hospital Devices
General Hospital Devices Branch

Device Name: Arrow High Flow Administration Set with Blood Filter and Extension Set

Product To Which Compared (510(K) Number If Known): High Flow Administration Set (K861275)

YES NO

	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: 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.

See attached review memorandum.

9

Certified Mail

January 18, 1996

RECEIVED

23 JAN 96 09 26

ARROW
INTERNATIONAL

Richard Galgon
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-420)
9200 Corporate Boulevard
Rockville, MD 20850

FDA/CDRH/OCE/DHC

3000 Bernville Road
Reading, PA 19605

Mailing Address:
P.O. Box 12888
Reading, PA 19612

(610) 378-0131
FAX: (610) 374-5360

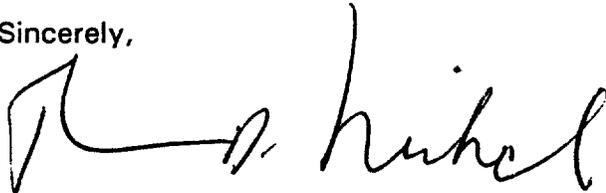
RE: 510(k) Premarket Notification K953746
Arrow High Flow Administration Set with Blood Filter and Extension Set

Dear Mr. Galgon:

This letter is in response to our phone discussion today.

- We will add the following statement to the product lid copy:
"This set contains DEHP plasticizer"
- We will assure that the device meets the following EtO residual limits before release for shipment:
ethylene oxide - 25 ppm
ethylene chlorohydrin - 25 ppm
ethylene glycol - 250 ppm
- The 510(k) numbers applicable to the products in the Arrow emergency fluid resuscitation device brochure are as follows:
 - Trauma kit containing sheath introducer - K780532 and K7811846
 - Peritoneal Lavage kit - K811627
 - Rapid infusion exchange kits with sheath introducers and devices - K780532 and K781846
 - High Flow Fluid administration set - K861275
 - Emergency Infusion devices - K840455

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

c: C. Botterbusch

96003tr

10

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Memorandum of Telephone Conversation

Date: January 18, 1996

Between: Richard E. Galgon, Biomedical Engineer, CDRH/ODE/DDIGD/GHDB, (HFZ-420)

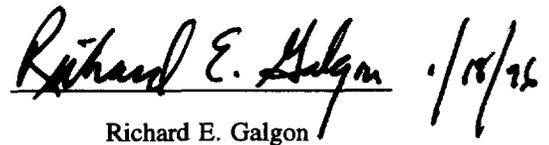
And: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Control
(610) 478-3137

Subject: K953746 Arrow High Flow Administration Set with Blood Filter and Extension Set

I contact Mr. Nickel in response to the additional information received December 5, 1995. I requested the following additional information which was not provided in the response:

1. references to 510(k) document numbers under which the devices and kits promoted in the document titled "Arrow Emergency Fluid Resuscitation Devices" received marketing clearance;
2. a statement indicating the EtO residual limits for the subject device will be 25, 25, and 250 ppm for EtO, EtC, and EtG, respectively; and
3. a statement indicating the following statement will be added to the labeling: "This set contains DEHP plasticizer."

Mr. Nickel agreed to provide the information as requested.


Richard E. Galgon

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

December 06, 1995

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K953746
Product: ARROW HIGH FLOW
FLUID
ADMINISTRATION
SET W/BLOOD

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

K953746 / S1

Certified Mail

P.O. Box 12888
Reading, PA 19612

November 30, 1995

ARROW
INTERNATIONAL

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

3000 Bernville Road
Reading, PA 19605
(610) 378-0131
FAX: (610) 374-5360

RE: 510(k) Premarket Notification K953746
Arrow High Flow Administration Set with Blood Filter and Extension Set

Dear Mr. Galgon:

(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



(b) (4)



If you have any questions, please call me direct at 610/478-3137, or FAX at 610/478-3172.

Sincerely,



Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

9599atr

18
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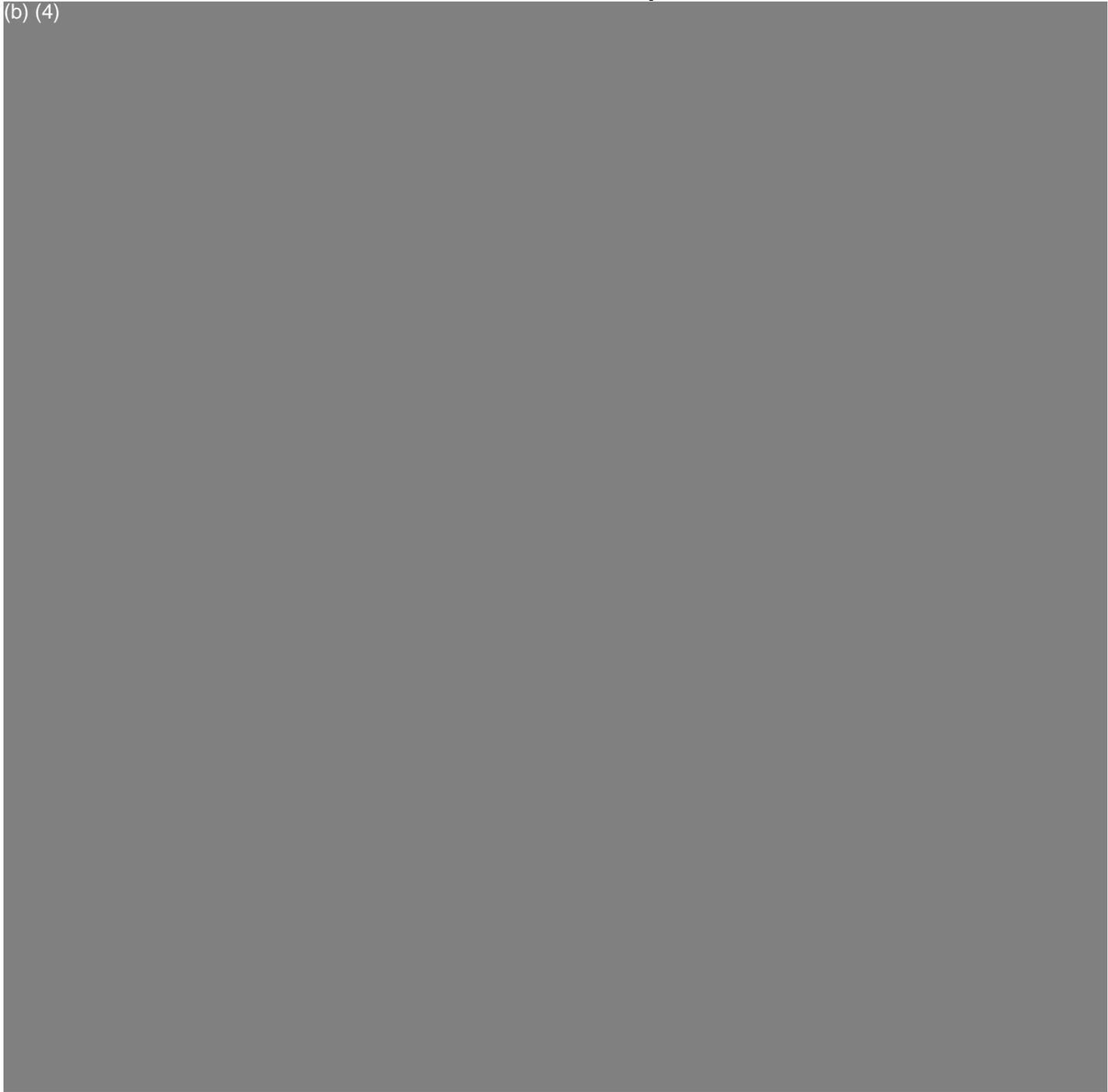
ATTACHMENT 1

197

AML-002
Issue Date: 01/26/95
Supersedes: 05/14/92
Applies to: B
Page 1 of 3

ARROW INTERNATIONAL, INC.

(b) (4)



20
8

AML-002
Issue Date: 01/26/95
Supersedes: 05/14/92
Applies to: B

(b) (4)



AML-002

Issue Date: 01/26/95

Supersedes: 05/14/92

Applies to: B

Page 2 of 2

(b) (4)



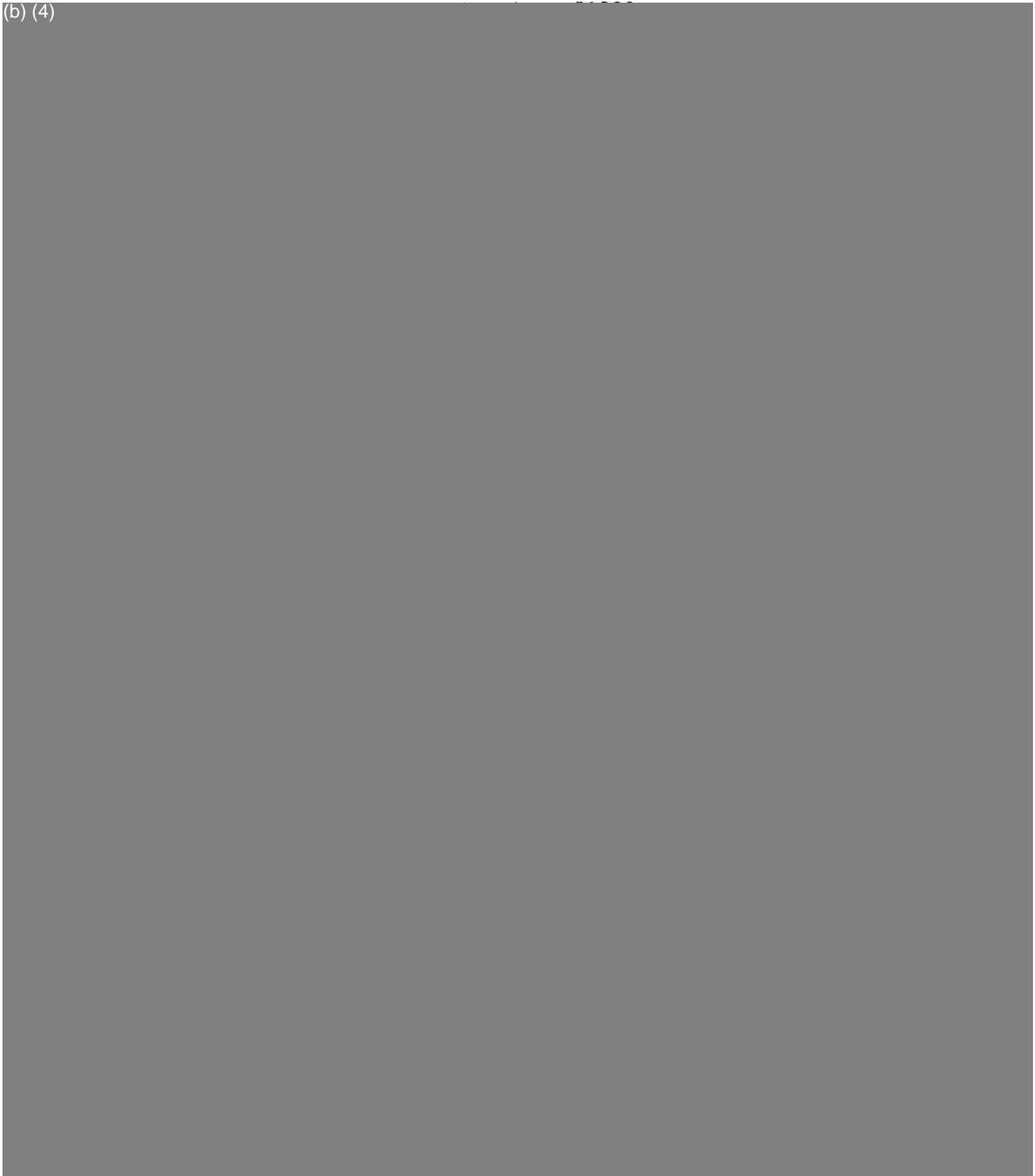
ATTACHMENT 2



AML-033
Issue Date: 11/16/92
Supercedes: NA
Applies to: B
Page 1 of 2

ARROW INTERNATIONAL, INC.

(b) (4)

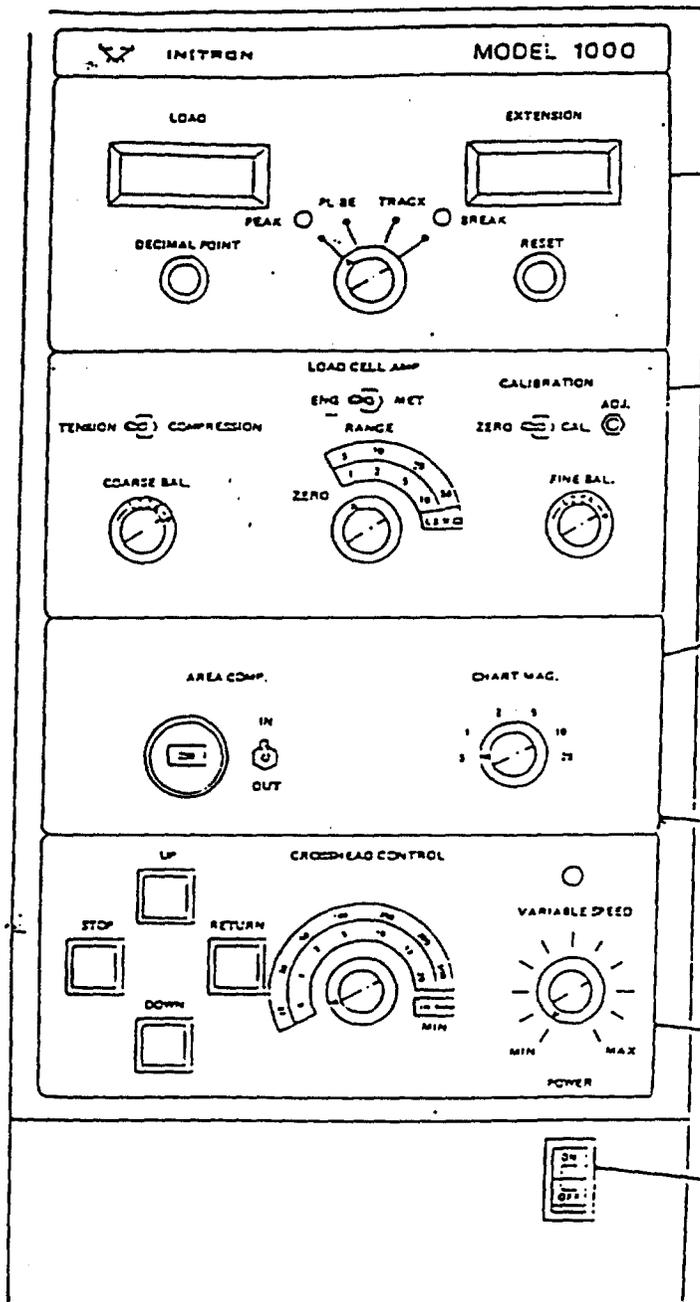


AML-033
Issue Date: 11/16/92
Supercedes: NA
Applies to: B
Page 2 of 2

(b) (4)



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The function of each subsection of the Model 1000 console is defined below.

READOUT PANEL - provides the user with a numerical readout of specimen loading and extension. The type of reading is selected by a 4-position function switch before starting a test.

LOAD CELL AMPLIFIER - signal conditions and amplifies the output of the weigh beam transducer to produce an accurately calibrated output for driving the load readout or an optional recorder.

AREA COMP. - the Area Compensator enables the output load signal to be proportional to stress by setting a precision potentiometer in proportion to the specimen cross-sectional area.

CHART MAG. - the Chart Magnification switch provides a selection of ratios between the chart advance on an optional recorder and the extension of the moving crosshead.

CROSSEAD CONTROL - provides the controls for the user to select the speed and direction of the moving crosshead.

POWER - main power switch for the model 1000 system.

Handwritten signature
14

AML-033
Attachment 2
Page 1 of 3

TESTING PARAMETERS TABLE

(b) (4)



AML-033
Attachment 2
Page 2 of 3

(b) (4)



(b) (4)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 27 1995

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

Re: K953746
Arrow High Flow Administration Set with Blood Filter and
Extension Set
Dated: July 18, 1995
Received: August 10, 1995

Dear Mr. Nickel:

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 device marketed prior to May 28, 1976, the enactment date of the Medical Device Amendments, based solely on the information you provided. In order for us to complete the review of your submission, we require the following information:

(b) (4)



Page 2 - Mr. Nickel

(b) (4)



Page 3 - Mr. Nickel

(b) (4)



Page 4 - Mr. Nickel

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(f) and (h), 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 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

Page 5 - Mr. Nickel

If you have any questions concerning the contents of this letter, please contact Mr. Richard E. Galgon 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.

Sincerely yours,



Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health



Mr. Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International, Incorporated
3000 Bernville Road
Reading, Pennsylvania 19605

Re: K953746
Arrow High Flow Administration Set with Blood Filter and
Extension Set
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(b) (4)



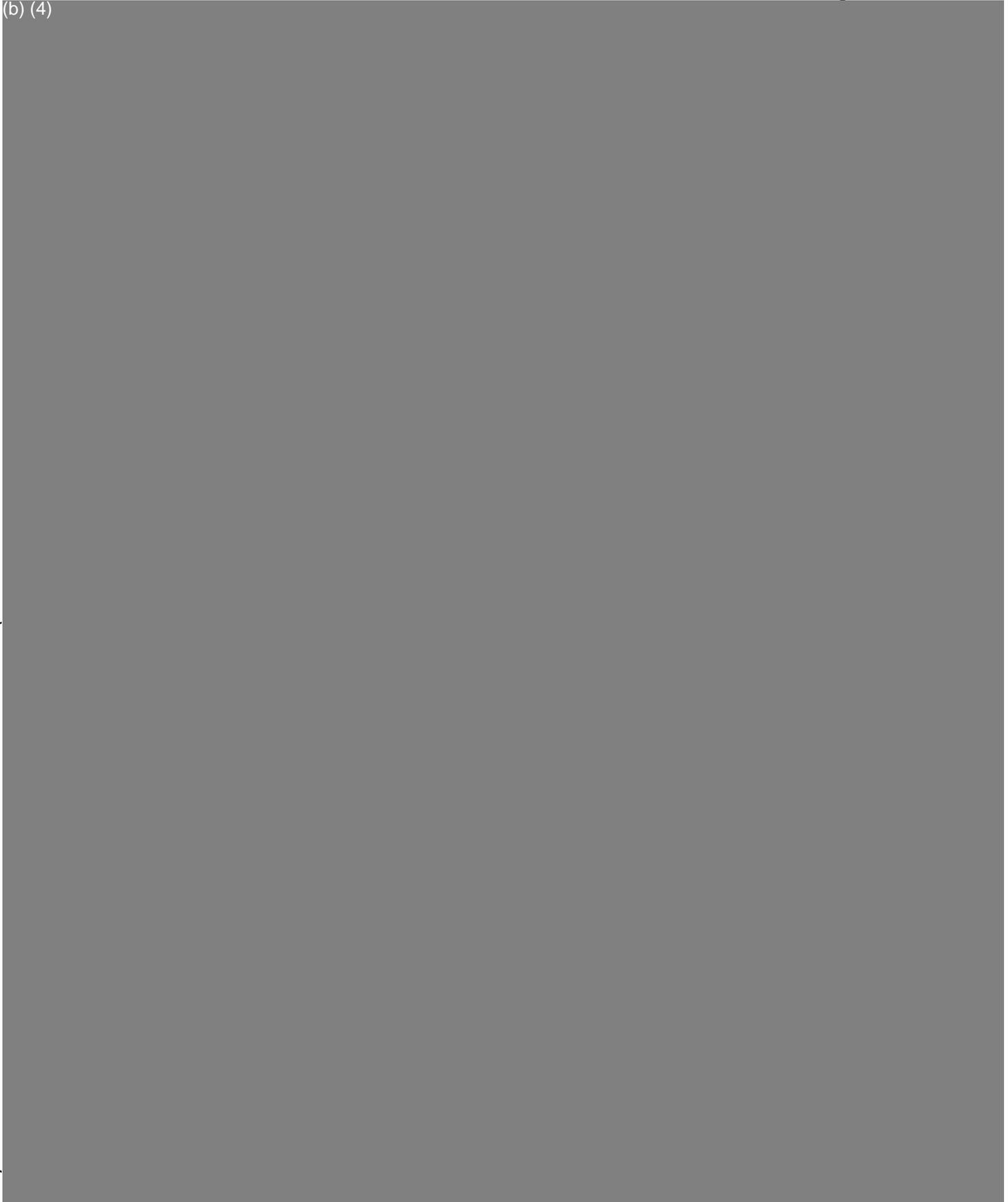
Page 2 - Mr. Nickel

(b) (4)



Page 3 - Mr. Nickel

(b) (4)



Page 4 - Mr. Nickel

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Page 5 - Mr. Nickel

If you have any questions concerning the contents of this letter, please contact Mr. Richard E. Galgon 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.

Sincerely yours,

Timothy A. Ulatowski
Acting Director
Pilot Division
Office of Device Evaluation
Center for Devices and
Radiological Health

FILE
COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
Z420	R. Galgon	10/27/95						
MEZ-42	Nickel	10/27/95						

U.S. GOVERNMENT PRINTING OFFICE 1991-519-771

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-420 DDIGD-Pilot Division
D.O.

d/t:
f/t:HFZ-420:RXG:Michele:10/26/95

C/D



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

10/25/95

From

REVIEWER(S) - NAME(S)

Richard E. Galgan

Subject

510(k) NUMBER

K953746

To

THE RECORD -- It is my recommendation that the subject 510(k) Notification:

- Is substantially equivalent to marketed devices.
- Requires premarket approval. NOT substantially equivalent to marketed devices.
- Requires more data. *Send hold letter*
- 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

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

The submitter requests under 21 CFR 807.95: No Confidentiality
 Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class:

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

REVIEW: Uou Nakayama SA PXC
(BRANCH CHIEF)

GHDB
(BRANCH CODE)

10/27/95
(DATE)

FINAL REVIEW: Uou Nakayama SA PXC
(DIVISION DIRECTOR)

10/27/95
(DATE)

Revised 3/8/95

cl

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

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

Date: October 25, 1995

To: The Record
From: Richard E. Galgon, Biomedical Engineer

Office: HFZ-420
Division: DDIG/GHDB

Sponsor: Arrow International
 3000 Bernville Road
 Reading, PA, 19605

Contact: Thomas D. Nickel
 Vice President, Regulatory Affairs and Quality Assurance
 (610) 378-0131

Device Name: Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200)

I. Purpose

The referenced premarket notification represents an intention by the sponsor to introduce into interstate commerce a new medical device to be known as the Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200).

II. Narrative Device Description

1.0 Intended Use. The sponsor has described the device as an administration set, but has not provided a statement of intended use to include all indications for use.

2.0 Device Description.

Summary Information

Life-supporting or life-sustaining?	No
Implant (short-term or long-term)?	No
Sterile?	Yes
Single use?	Yes
Prescription use?	Yes
Home use or portable?	Yes
Drug or biologic component?	No
Kit?	No
Software-driven?	No
Electrically operated?	No
Truthful and accuracy statement?	Yes

Summary of safety and effectiveness?	No
510(k) certification?	Yes

The Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set (Model HF-01200) consists of two components, the administration set with blood filter and the extension set. The administration set from proximal to distal end consists of two vented blood spikes (acrylic, DR 100, Rohm & Haas) connected through a Y-site (PVC, MIXVIL AM/20-W17, TPV Argenta) to a drip chamber (PVC, MIXVIL AM/20-W17 and AM/88-W17, TPV Argenta) containing a 260 µm filter (polypropylene, MOPLEN S30/G, Himont). The drip chamber is attached to the administration set tubing (PVC, MIXVIL AM/14, TPV Argenta). Incorporated into the administration set tubing are two in-line luer lock T-pieces (PVC, MIXVIL AM/90-W17, TPV Argenta), and one in-line injection site. The injection site is constructed from polypropylene (NOVOLEN 1100 HX, BASF Germany), natural latex rubber (Mixture 61-FU, Farmagossa, Italy), and PVC (MIXVIL AM/90-W17, TPV Argenta). The administration set terminates in a female luer lock (MIXVIL AM/90-W17, TPV Argenta).

From proximal to distal end, the extension set consists of a rotating male luer lock (ABS, TERLURAN KR 2802TR, BASF Germany) attached to the extension tubing (PVC, MIXVIL AM/14, TPV Argenta), and terminates with a female luer lock (MIXVIL AM/90-W17, TPV Argenta). The extension set incorporates one in-line injection site identical to those used in the administration set. Both sets utilize tubing pinch clamps. See Attachment 2 for device drawings.

2.1 Sterilization. The subject device will be sterilized to a SAL of 10^{-6} using EtO gas. The sponsor indicates EtO residual levels will be in accordance with the FDA proposed regulation of June 23, 1978 and ISO/DIS 10993-7.2; however, the sponsor has not indicated a classification for the device with respect to these references.

2.2 Pyrogenicity. The device will be labeled non-pyogenic. Pyrogenicity will be verified using either the LAL test or USP pyrogen test.

2.3 Packaging. The device will be unit packed in a polystyrene tray topped with a Tyvek lid.

2.4 Labeling. The sponsor has provide package labels, Instructions for Use, and promotional literature for the device. See below for comments.

III. Correspondence

The referenced premarket notification was received on August 10, 1995. The submission appears to have been received by the Center for Biologics Evaluation and Research (CBER) on July 21, 1995. It was then forwarded to CDRH and received as indicated.

On October 16, 1995, I contacted Mr. Nickel, Vice President of Regulatory Affairs and Quality Assurance. We discussed the availability of test data to support claims made in the promotional literature provided in Attachment 1. Following, I sent him a facsimile outlining the issues and concerns I had regarding this application (see telephone memorandum).

On October 20, 1995, I received a facsimile back in response. Mr. Nickel informed me they would not be able to respond to the concerns before November 1, 1995. Therefore, he requested I issue a hold letter detailing the outstanding issues. This was verified by telephone on October 24, 1995.

(b) (4)



V. Recommendation

I recommend the referenced premarket notification be placed on hold until the sponsor provides additional information to address those deficiencies outline in my facsimile dated October 16, 1995, and above.

Richard E. Galgon 10/25/95

Richard E. Galgon

41

ARROW

International, Inc.
3000 Bernville Road
Reading, PA 19605 USA
610/478-3137
FAX: 610/478-3172

PLEASE DELIVER THE FOLLOWING PAGE(S) TO:

NAME: Richard Galgon
301/594-2358

FROM: Thomas D. Nickel

RE: Your FAX of 10/16/95 - K953746

DATE: October 20, 1995

Total number of pages including cover letter **1**



We will not be able to respond by November 1, 1995, so go ahead and issue the letter. I am sorry we can't move that quickly, but the individuals involved in the project are not in the office until after November 1.

I appreciate your calling us on this and providing the opportunity to respond quickly.

Tom Nickel

*Verified by telephone 10/24/95
REY*

yle

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Memorandum of Telephone Conversation

Date: October 16, 1995

Between: Richard E. Galgon, Biomedical Engineer, CDRH/ODE/DDIG/GHDB _____

And: Thomas D. Nickel
Vice President, Regulatory Affairs and Quality Assurance
Arrow International
(610) 378-0131

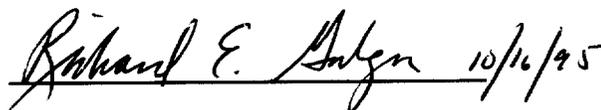
Subject: K953746 Arrow High Flow Fluid Administration Set with Blood Filter (P/N HF-01200)

I called Mr. Nickel in order to obtain information which was necessary to continue the review of the referenced premarket notification. We discussed the availability of test data to support the claims made in the promotional literature provided in Attachment 1.

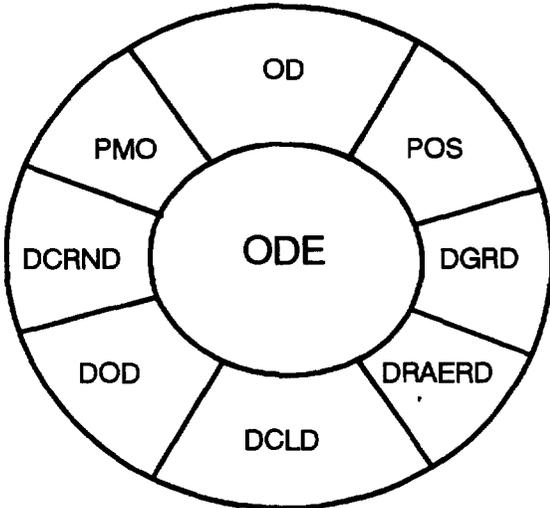
I informed Mr. Nickel I would send a facsimile outlining the issues and concerns I had regarding the referenced premarket notification. I requested a response by November 1, 1995, to provide sufficient time for review within this review cycle. I also requested that he contact me as soon as possible if any of the information being requested was not available in their files to allow me to issue a written hold letter.

Finally, I requested he contact me if he needed any clarification of the information being requested in the facsimile.

Following, I sent him the attached facsimile.


Richard E. Galgon

**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF GENERAL AND RESTORATIVE DEVICES (PILOT)
9200 CORPORATE BOULEVARD, HFZ-410
ROCKVILLE, MARYLAND 20850**



FROM: Richard E. Galgon

DATE: October 16, 1995

NO. OF PAGES: 3

PHONE NO: (301) 594-1287

FAX NO: (301) 594-2358

TO: Thomas Nickel, Vice President, Regulatory Affairs and Quality Assurance

FAX NO: (610) 478-3172

SUBJECT: K953746 Arrow High Flow Administration Set with Blood Filter

ADDITIONAL COMMENTS:

As we discussed today, I am forwarding this facsimile containing the issues and concerns I have regarding the referenced 510(k). Please provide your response in the form of a facsimile, if possible, followed by a hardcopy submitted to the Document Mail Center (DMC). If you are unable to provide a facsimile copy, then provide only a hardcopy to the DMC. Your response should be received by November 1, 1995, to allow sufficient time for review within this review cycle. I am faxing this request because, as we discussed, I believe the information being requested is available in your files. If any of the information is unavailable in your files, please contact me as soon as possible in order to allow me to issue you a written hold letter. If you have any questions or need clarification to the questions being asked, please contact me at (301) 594-1287. Thanks for your cooperation.

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

October 16, 1995

From: Richard E. Galgon

To: Thomas Nickel

Subject: K953746 Arrow High Flow Administration Set with Blood Filter

1. (b) (4)

2.

3.

4.

5. **The literature titled "Arrow Emergency Fluid Resuscitation Devices" identifies other Arrow products besides the subject device.**

- **Provide references to 510(k) document numbers under which these devices and kits were cleared for marketing.**
- **Provide test protocols and results to support all claims made.**

6. **The instructions for use for the subject device provided in Attachment 1 identify a 4-spike model (P/N HF-01201).**

- **Provide a complete description of this model including engineering drawings, material specifications, operating characteristics, and labeling. Indicate whether or not the sterilization, pyrogenicity, and packaging information contained in the application is also applicable to Model HF-01201.**
- **Either provide test protocols and results to support the performance of this model or a valid scientific justification as to why the testing conducted on the Model HF-01200 device is**

representative of the Model HF-01201.

7. **Indicate whether or not the PVC used in the sets contains DEHP plasticizer. Modify the device labeling to indicate its presence, if applicable.**
8. **Were all available components (e.g., luer locks, tubing, filters, etc.) incorporated into the sets for biocompatibility testing? If not, indicate which components were included in the ground sets, and justify the exclusion of those components which were not included.**
9. **You have indicated that the subject devices will be sterilized using EtO gas and the EtO residual limits will be in accordance with the FDA proposed regulation of June 23, 1978 and ISO 10993-7.2. Either specifically state the EtO residual levels which you will meet for ethylene oxide, ethylene chlorohydrin, and ethylene glycol in ppm or identify the device class as listed in the referenced FR notice under which your device falls.**

PILOT Division Screening Checklist
for Premarket Notifications [510(k)s]

ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: <i>Arrow High flow fluid Admin Set w/ Blood Filter + Extension Set</i> <i>K 953746</i>	
Submitter Name: <i>Arrow Intl., Inc.</i>	
General Content of a 510(k)	MISSING INFORMATION
<p>1.* <u>General Information:</u> a) trade name, b) common name, c) establishment registration number, if known d) address of manufacturing sites, e) FDA assigned device class (I,II,III), f) FDA review panel, if known, g) state if submission is for a new device or modification of a legally marketed device, h) identify legally marketed device(s) to which applicant claims equivalence of submitted device, i) applicant's name and address.</p> <p>COMMENT:</p>	
<p>2.* <u>Safe Medical Device Act of 1990 Requirements:</u> a) 510(k) summary or statement (ALL devices) b) Truthful and Accurate Statement (see attached) c) Class III Certification & Summary (only for Class III devices).</p> <p>COMMENT:</p>	
<p>3.* <u>Proposed Labeling:</u> a) device and package labels, b) package insert, c) statement of intended use, d) promotional material that may accompany device.</p> <p>COMMENT:</p>	(d)
<p>4.* <u>Description of Device (or modification):</u> diagrams, engineering drawings, or photographs.</p> <p>COMMENT:</p>	

<p>5. <u>Comparison Information</u>: similarities and differences to named legally marketed equivalent device(s), a comparison table of attributes is recommended and should compare and contrast: a) labeling, b) intended use, c) specifications, d) materials, e) performance (bench, animal, clinical) data (as needed), f) analysis of comparable safety and effectiveness.</p> <p>COMMENT:</p>	<p>(c) (d)</p>
<p>6. <u>Biocompatibility Data</u>: needed for all direct or indirect patient or user-contacting materials per Tripartite Guidance or ISO standard, or provide a certification that materials are identical to legally marketed devices for same intended use.</p> <p>COMMENT:</p>	
<p>7. <u>Sterilization Information</u>: a) sterilization method, b) Sterility Assurance Level, c) type of packaging, d) pyrogen test method, e) EtO residues, f) radiation dose, g) statement of validation method.</p> <p>COMMENT:</p>	
<p>8. <u>Software Validation & Verification</u>: according to FDA guidance: a) hazard analysis, b) level of concern, c) development documentation, d) certification.</p> <p>COMMENT:</p>	
<p>9. <u>Information Recommended in FDA Guidance</u>: There is an FDA guidance document for this device that recommends additional data.</p> <p>COMMENT:</p>	
<p>10. <u>Kit Information</u>: see attachment if this device is a kit.</p> <p>COMMENT:</p>	

B

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20856

August 14, 1995

ARROW INTL., INC.
3000 BERNVILLE ROAD
READING, PA 19605
ATTN: THOMAS D. NICKEL

510(k) Number: K953746
Received: 10-AUG-95
Product: ARROW HIGH FLOW
FLUID ADMINISTRATION
SET W/BLOOD FILTER &
EXTENSION SET

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 December 14, 1994, FDA published a regulation entitled "Medical Devices; Substantial Equivalence; 510(k) Summaries and 510(k) Statements; Class III Summaries; Confidentiality of Information." The regulation took effect March 14, 1995. Please note that this regulation includes a requirement that all submitters provide a statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted. 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 at the number 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).

If you have 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 the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or call 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

1953/46

MEMORANDUM

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**

DATE: August 9, 1995
FROM: CBER Document Control Center, HFM-99
SUBJECT: Transfer of 510(k) or PMA
TO: Document Mail Center, HFZ-401
Center for Devices and Radiological Health
Piccard Building, Room 281

At the request of the Division of Blood Establishment and Product Applications and in accordance with the CBER/CDRH Inter-Center Jurisdictional Agreement, we are forwarding the attached 510(k) or PMA. In their evaluation, this submission is under CDRH jurisdiction and was incorrectly sent to CBER by the sponsor. Please sign this memorandum acknowledging receipt and return one copy to the CBER Document Control Center (HFM-99).

SPONSOR: Arrow International
TRADE NAME: Arrow High Flow Fluid Administration Set
DATE OF LETTER TO SPONSOR: August 2, 1995
NUMBER OF COPIES FORWARDED: 2

Tom W. Dudley
CBER Document Control Center

RECEIVED IN CDRH BY : 

PLEASE RETURN ONE COPY TO CBER DOCUMENT CONTROL CENTER - HFM-99

DCC-105 -11/93

55
40
II

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DUPLICATE

AUG 02 1995

Thomas D. Nickel
 Arrow International
 3000 Bernville Road
 Reading, PA 19605

Trade Name: Arrow High Flow Fluid Administration Set
 Dated: July 18, 1995
 Received: July 21, 1995
 Classification: II

Dear Mr. Nickel

The Center for Biologics Evaluation and Research (CBER) of the Food and Drug Administration (FDA) has received your section 510(k) notification of intent to market the product referenced above. We have determined that the device meets the definition of a "device" as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act.

The Center for Devices and Radiological Health (CDRH) is responsible for review of this type of device and therefore, CBER will transfer your premarket notification to CDRH for review. If you have any questions regarding this letter, please contact Mr. Martin E. Northern of the Division of Blood Applications (DBA), CBER at (301) 594-6487.

Sincerely yours,

Richard M. Lewis, Ph.D.
 Acting Chief
 Devices and Hematologic Products Branch
 Division of Blood Applications
 Office of Blood Research and Review
 Center for Biologics
 Evaluation and Research

PREPARED BY: HFM-380: MNorthern 07/31/95(BK950036.ack)

This submission was received by CBER/DBA on July 21, 1995. It has been transferred to CDRH

SL

**FILE
 COPY**

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFM-380	<i>North</i>	7/21/95						
380	<i>Lewis</i>	8/2/95						
HFM 380	<i>ROBINSON</i>	8/2/95						

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

Public Health Service

MEMORANDUM

Date: July 31, 1995

From: Mary Gustafson, Director, DBA, CBER, HFM-370

Subject: Transfer of 510(k) BK950036

To: Philip J. Phillips, Deputy Director, ODE, CDRH, HFZ-400

Firm: Arrow International

We have forwarded the 510(k) to CDRH for review. We have written the firm advising that we have transferred the 510(k) to your office for review.

If you have any questions regarding this transfer you may call Martin E. Northern at (59)4-6487. Thank you.

Attachment

LOG NUMBER L95008173
PRE-MARKET NOTIFICATION BK _____
VOLUME 10/1 DATE 18 Jul 95
COPY NUMBER _____ ORIGINAL X
Return to CBER DCC - HFM-99

ARROW
INTERNATIONAL

3000 Bernville Road
Reading, PA 19605

Mailing Address:
P.O. Box 12888
Reading, PA 19612

(610) 378-0131
FAX: (610) 374-5360

July 18, 1995

Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20853
Attention: Ms. Sukza Hwangbo (HFM-375)

Re: Enclosed 510(k) Premarket Notification -
Arrow High Flow Fluid Administration Set

Dear Ms. Hwangbo:

As required by Section 510(k) of the Medical Device Amendments of 1976 and in conformance with 21 CFR 807, we are providing you with prior notice that we propose to market an Arrow high flow fluid administration set, the details of which are described in the attached premarket notification submission (2 copies).

If you have any questions, please call me at the direct phone number listed in the submission.

Sincerely,

Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance

TDN/crk

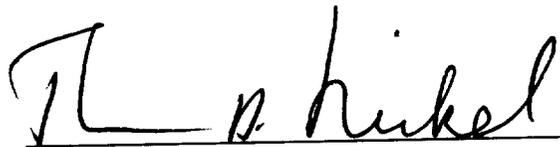
enclosure

6019ltr

RECEIVED
10 AUG 95 16 03
FDA/CDRH/OCE/DNC

**510(k) PREMARKET NOTIFICATION
ARROW HIGH FLOW FLUID ADMINISTRATION SET**

Date: July 18, 1995
Submitted by: Thomas D. Nickel
Vice President, Regulatory Affairs
and Quality Assurance
Arrow International, Inc.
P. O. Box 12888
3000 Bernville Road
Reading, PA 19612



FAX: (610) 478 3172
Direct Phone: (610) 478-3137



510(k) Premarket Notification
Arrow High Flow Fluid Administration Set
July 18, 1995
Page 2

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14. Truthful and Accurate Statement.....	6

Attachments

1. Labeling - Arrow HF-01200 High Flow Administration Set, plus advertising brochures
2. Drawings and a list of components of the device.
3. Product qualification reports.
4. Biocompatibility testing.

60
2

510(k) Premarket Notification
Arrow High Flow Fluid Administration Set
July 18, 1995
Page 3

Contained herein is information regarding the Arrow HF-01200 High Flow Fluid Administration Set as required by Section 510(k) of the Medical Device Amendments of 1976 and 21 CFR 807.

1. Device Name

Trade Name: Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set

2. Establishment Registration Numbers

Owner/Operator - Arrow International, Inc.
P. O. Box 12888
3000 Bernville Road
Reading, PA 19612
FDA #2518433

Manufacturing and Sterilization Location

Arrow International, Inc.
312 Commerce Place
Randleman, NC 27317
FDA #1036844

3. Classification

The device is an Intravascular Administration Set 80 FPA, classified in Class II at 21 CFR 880.5440, Intravascular Administration Set. This is a General Hospital division classification.

4. Section 514 Compliance

To the extent applicable at this time we submit that we are in compliance with the requirements of Section 514 as to this device.

5. Labeling, Advertising, and Directions for Use

The labeling and directions for use for the device are appended as Attachment 1.E. Two advertising brochures involving this product are also included in the same attachment.

6. Background to the Development of the Device

From November 1986 to date we have sold a high flow blood and fluid administration set manufactured by Migada, Ltd, Rehovot, Israel. We receive the product bulk non-sterile, and package and EtO sterilize it at our Randleman, NC manufacturing facility. The supplier, Migada holds the 510(k) premarket notification, K861275, found substantially equivalent 6/2/86.

510(k) Premarket Notification
Arrow High Flow Fluid Administration Set
July 18, 1995
Page 4

We have found an alternate supplier who can provide the same exact set at a significant cost savings, and are submitting this premarket notification to cover that device. The supplier of the bulk sets is a long time Arrow distributor (and also manufacturer of devices and device components), Kimal Scientific Products Ltd., Uxbridge, Middlesex, England.

The new set is essentially identical in design and performance to the Migada set.

7. Description of the Device

Refer to Attachment 2 for drawings and a list of components for the device. The predicate device is comparable.

8. Substantial Equivalence

The device is substantially equivalent to the currently marketed Arrow product. It is essentially the same device in design, materials, dimensions, function, and labeling, with the only significant difference being the supplier.

Refer to Attachment 3 for a product qualification report which compares the device to the predicate device minimum specifications for tensile strength of all joints and flow rate testing.

Biocompatibility testing of the entire set ground into small pellets for testing yielded satisfactory results as required in the recent CDRH requirements for conformity to ISO 10993, Part 1 (as modified by CDRH) - see Attachment 4.

9. Statement of Similarities and/or Differences with the Marketed Device

As stated previously, the device is essentially identical to the predicate.

10. Applicability of Specific FDA Guidance Documents

While no CDRH guidance documents apply directly to blood and solution administration sets per se, the submission has been reviewed against the following CDRH documents to assure that all necessary information has been included:

- Division of General and Restorative Devices "Intravascular Catheter Initial Checklist"
- Division of General and Restorative Devices "Guidance on Premarket Notification [510(k)] Submissions for Short and Long-Term Intravascular Catheters"
- CDRH Blue Book memos on 510(k) decision tree and reviewer SE decision making checklist

WJ
4

510(k) Premarket Notification
Arrow High Flow Fluid Administration Set
July 18, 1995
Page 5

- CDRH 510(k) Refuse to Accept Policy and Checklist
- Addendum: How to submit a premarket notification [510(k)] - March 1995 - DSMA

11. Action Taken to Comply with Voluntary Standards

We are in compliance with two voluntary standards with respect to this device - ANSI/AAMI ST27-1988, Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices, and ANSI/HIMA MD70.1, 1983, American National Standard for Medical Material - Luer Taper Fittings - Performance.

12. Sterilization - Required Information

Since this is a sterile device, the following additional required information applies:

1. The device will be sterilized by 100% ethylene oxide, utilizing the overkill approach.
2. The sterilization cycle is the same single cycle utilized for all Arrow products in the same facility and vessels, and is described below.

ARROW INTERNATIONAL INC.
PRODUCT STERILIZATION

STERILANT: 100% Ethylene Oxide

PRECONDITIONING: A minimum of 12 hours residence time at 43°C (38 - 48°C) and 60% relative humidity (35 - 95%) in a preconditioning chamber.

STERILIZATION CYCLE:

- Initial vacuum draw to 2 PSIA ± 0.5 PSIA.
- Nitrogen wash to 13.5 PSIA ± 0.5 PSIA followed by a vacuum draw to 2 PSIA ± 0.5 PSIA.
- Steam conditioning at 43°C ± 5°C, 2.8 PSIA ± 0.2 PSIA (45 - 80%) for 65 minutes.
- Ethylene Oxide exposure at 43°C ± 5°C, 7.5 PSIA ± 0.5 PSIA for 240 minutes ± 5 minutes. 540 mg/L gas concentration (460-625 mg/L).
- Post vacuum draw to 2 PSIA ± 0.5 PSIA.
- Nitrogen wash to 13.5 PSIA ± 0.5 PSIA followed by a vacuum draw to 2 PSIA ± 0.5 PSIA.
- Air wash to 13.5 PSIA ± 0.5 PSIA followed by a vacuum draw to 2 PSIA ± 0.5 PSIA.
- Final air inbled to atmospheric pressure

The entire cycle from entry to exit runs 9-9 1/2 hours.

AERATION A minimum of 8 hours residence time at 43°C (38 - 48°C) in an aeration chamber.

510(k) Premarket Notification
Arrow High Flow Fluid Administration Set
July 18, 1995
Page 6

(b) (4)



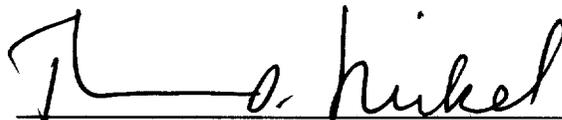
3. The sterility assurance level of the device is 10^{-6} .
4. The unit packaging for the device is a Tyvek lid with a high impact polystyrene tray.
5. Our release limits for EtO residuals are as stated in the FDA proposed regulation of June 23, 1978 and ISO/DIS 10993-7.2.
6. The product is labeled non-pyrogenic and is tested for pyrogenicity by either the Limulus Amebocyte Lysate (LAL) test or USP pyrogen test.

13. 510(k) Statement

I certify that I, Thomas D. Nickel, will make available all information included in this premarket notification on safety and effectiveness that supports a finding of substantial equivalence within 30 days of request by any person except for confidential, trade secret information, which will be expunged. The information I agree to make available does not include confidential patient identifiers.

14. Truthful and Accurate Statement

I certify that in my capacity as Vice President, Regulatory Affairs and Quality Assurance of Arrow International, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Thomas D. Nickel
July 18, 1995

5350

1

MultiDex

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

ATTACHMENT 1

663

PMS #192

PRODUCT NO. HF-01200

ARROW

HIGH FLOW FLUID ADMINISTRATION SET

With Blood Filter and Extension Set

CONTENTS:

- ONE Two-Spike Large Bore (8.5 FR min. I.D.) Fluid Administration Set with Blood Filter and Extension Set
- ONE Instruction Sheet

PMS #192

CAUTION: U.S.A. FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN. WARNING: PRIOR TO USE READ ALL PACKAGE INSERT CAUTIONS AND INSTRUCTIONS.

DO NOT USE IF PACKAGE HAS BEEN PREVIOUSLY OPENED OR DAMAGED. CONTAINS NO MEDICATION. STERILIZED BY ETHYLENE OXIDE. DISPOSABLE - DO NOT RESTERILIZE. FLUID PATH COMPONENTS ARE NON-PYROGENIC.

Manufactured by:

ARROW

INTERNATIONAL, INC.

3000 Bernville Road
Reading, Pennsylvania 19605

IF-01200-106B

8.5 Fr.

MINIMUM ID

PRODUCT NO.

HF-01200

LOT CONTROL NO.

PRODUCT NO. HF-01200

ARROW

PEEL TO OPEN

HIGH FLOW FLUID ADMINISTRATION SET

STERILE

With Blood Filter and Extension Set

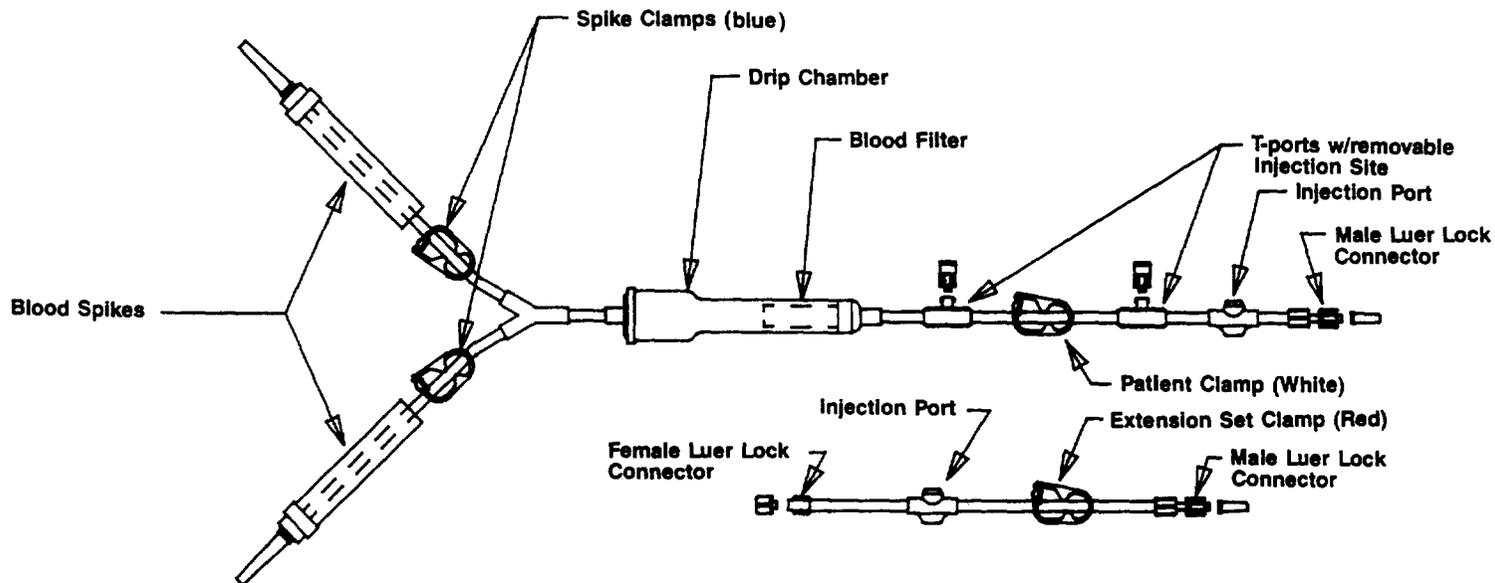
8.5 Fr.

ARROW

HIGH FLOW FLUID ADMINISTRATION SET WITH BLOOD FILTER AND EXTENSION SET

A) SUGGESTED PROCEDURE - USE STERILE TECHNIQUE. Change Within 24 hours.

It is recommended that high flow tubing be primed and hanging prior to trauma situation to facilitate solution therapy in a most efficient manner.



A. To prime set and administer solution (see Fig.):

- 1) Remove Arrow high flow administration set and extension set from package. Remove male and female Luer caps and blood spike caps. Attach extension set to high flow set if desired. Twist to secure Luer lock.
- 2) Open one blood spike clamp and extension set clamp. Close all other clamps. Prepare solution bag.
- 3) Insert open spike into solution container and hang container.
- 4) Invert drip chamber and open patient clamp. Let drip chamber fill to top of filter (about half way up drip chamber). Close patient clamp and return drip chamber to normal position.
- 5) Open patient clamp to fill patient tubing and expel air. Tap drip chamber to remove air trapped in filter. CAUTION: DO NOT ALLOW AIR TO REMAIN IN TUBING. ALL AIR MUST BE PURGED TO AVOID AIR EMBOLISM COMPLICATIONS. NOTE: It may be necessary to remove injection site caps at T-ports and flush solution through ports to purge all air from system.
- 6) Close patient clamp. Connect male Luer extension set (or high flow set, if not using extension set) to indwelling large bore catheter. (Arrow 8.5FR EID recommended - Contact Arrow International, Inc. for information, including instructions and cautions.) Twist to lock securely in position.
- 7) Regulate flow by adjusting patient clamp and/or extension line clamp. Check clamp periodically.
Note: If using 4-spike model (HF-01201), close blue clamp on primed filter branch and repeat above procedure to prime other filter.

B) To transfuse blood:

- 1) Prepare blood bag in the usual manner.
- 2) Prime set according to A.
- 3) Insert blood spike into outlet port of blood bag using a twisting motion. Close patient clamp.
- 4) Hang blood bag. NOTE: If packed cells are to be diluted, hold blood spike at 10 inches below solution spike. Open blood spike clamp and allow solution to enter blood bag until desired dilution is achieved. Then close solution spike clamp.
- 5) Fully open blood spike clamp (if not already open from dilution packed cells). Regulate flow with extension set clamp or with patient clamp. CAUTION: DO NOT SQUEEZE DRIP CHAMBER WHEN BLOOD SPIKE CLAMP IS OPEN.

C) To infuse multiple units of blood (packed cells):

- 1) Prepare second blood bag in usual manner.
- 2) Clamp off solution clamp and remove solution bag.
- 3) Attach second blood bag by inserting spike from solution bag, using a slight twisting motion.
- 4) Hang blood bag.
- 5) When 1st blood bag is empty, close off blood spike clamp and open second (full) blood spike clamp. Regulate flow through patient clamp.
- 6) One may continue alternating spikes in this manner until up to 4 units of blood are pressure infused (8 units if alternating spikes on 4-spike, HF-01201). CAUTION: DO NOT PRESSURE INFUSE MORE THAN 4 UNITS PACKED CELLS THROUGH A SINGLE BLOOD FILTER, SINCE THIS MAY CAUSE CLOGGING OF THE FILTER.
Note: Continuous infusion of diluted packed cells is possible utilizing the four spike HF-01201. Using the HF-01200, one must clamp off both spikes to change blood and solution bags, interrupting infusion.

D) Follow-up to large scale fluid administration:

The Arrow® High Flow Fluid Administration set is recommended for situations where high flow rates are required. Following volume resuscitation, when lower flow rates are desirable (less than 300cc/hr.), Arrow® set should be replaced by standard IV tubing. During Trauma resuscitation, T-ports may be used to track central venous pressure, in order to monitor resuscitation and rule out pericardial tamponade and tension pneumothorax. T-injection port may also be used to attach additional large bore infusion sets or standard IV sets to originally placed large bore line. Use extension set clamp to pinch off line when making all connections to avoid possible blood loss or air embolism complications. T-injection port and blue injection ports may be used for administration of medication.

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ARROW[®]
CAUTION

1. CAUTION: IN ORDER TO AVOID PROBLEMS ASSOCIATED WITH DISCONNECTS, IT IS RECOMMENDED THAT ONLY LUER LOCK CONNECTING DEVICES BE USED WITH THIS PRODUCT.
2. CAUTION: AMERICAN ASSOCIATION OF BLOOD BANKS RECOMMEND THAT ONLY .9% SALINE SOLUTION BE ADMINISTERED WITH BLOOD.*
* Reference: AABB standards 11th edition, section J3.200, pg 30.
3. CAUTION: AFTER INITIAL VOLUME RESUSCITATION, AMOUNT OF VOLUME ADMINISTERED MUST BE CAREFULLY CONTROLLED TO AVOID OVERLOAD COMPLICATIONS.
4. CAUTION: CHANGE ALL TUBING WITHIN 24 HOURS.
5. CAUTION: DO NOT PUNCTURE TUBING OR DRIP CHAMBER. TUBING WILL NOT RESEAL AND COULD CAUSE AIR EMBOLISM.

S-01200-105A

WJ
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clinical
part

FLOW TESTS OF RAPID INFUSION DEVICES INCLUDING ARROW HIGH-FLOW FLUID ADMINISTRATION SET.

Rapid fluid infusion can be an important addition for the treatment of patients with moderate to severe hypovolemic shock.

These tests were performed to compare the new Arrow High-Flow Fluid Administration Set with other fluid administration sets designed for higher than normal fluid flow.

This Technical Data Sheet compares the administration sets using clinically accepted methods for evaluating flow rates of fluids normally administered to hypovolemic patients.

Rapid fluid volume replacement for emergency fluid resuscitation must address problems of providing high flow rates.

The most important factor affecting the flow rate is the inside diameter of the tubing, fittings, and catheter. The Arrow HF-01200 High Flow Fluid Administration Set has a minimum internal diameter of 8.5 FR for all tubing and fittings. Therefore, the biggest flow restriction you will experience will be the catheter, not the blood lines, unless you're using an 8.5 FR inside diameter sheath or catheter.

FLOW STUDIES

The Arrow HF-01200 High Flow Fluid Administration Set was flow tested in three simulated clinical situations:

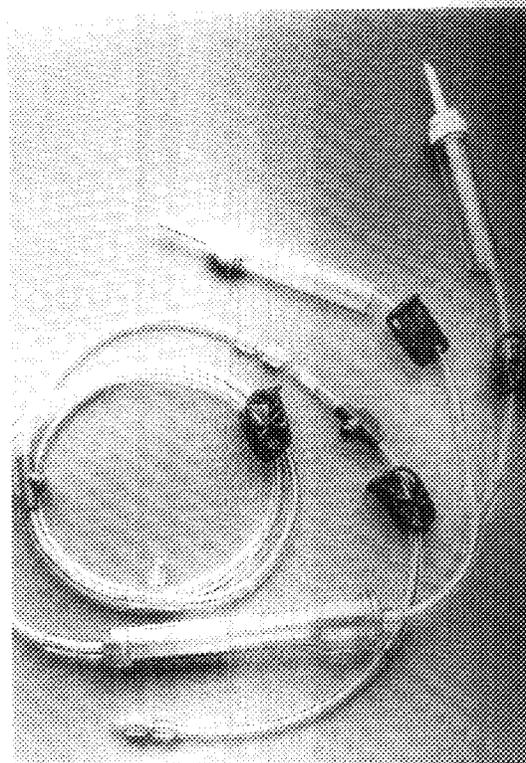
1. Saline gravity infused at a height of 85cm.
2. Saline pressure infused under 300mm Hg pressure.
3. Packed cells diluted and pressure infused at 300mm Hg.

For comparison, saline infusions were done with both the Arrow HF-01200 High Flow Fluid Administration Set and a Travenol ZC-00015 Solution Administration Set (Standard I.V. Set). The results obtained are shown in Graphs No. 1 and 2. In the blood administration studies, the Arrow HF-01200 was tested in conjunction with the Medex[®] MX882 Hi-Flow Trauma[™] Set and the Travenol 4C2194 Y-Type Blood-Solution Recipient Set. Refer to Graph No. 3.

The Arrow High-Flow Fluid Administration Set was designed to deliver larger quantities of fluid to the patient in a shorter time than other available fluid delivery sets.

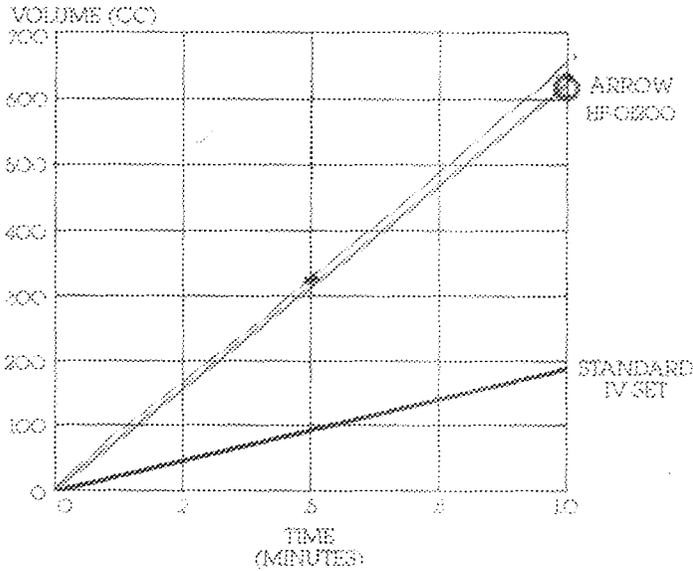
All component parts were checked carefully from their physical point of view as well as the medical, in order to ensure no decrease of flow due to physical phenomena.

The Arrow 8.5 FR Minimum I.D. Line delivers flow rates averaging 1257 ml/min, with flows as great as 1615 ml/min, 300 per cent higher than a standard infusion line.

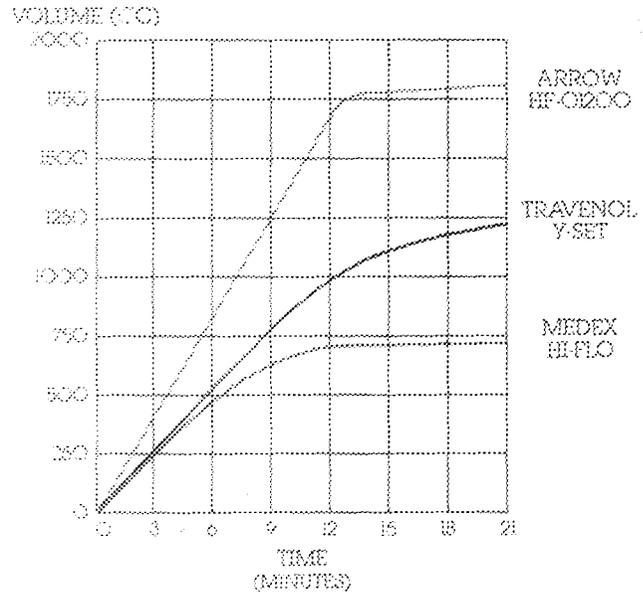


ARROW
INTERNATIONAL, INC.

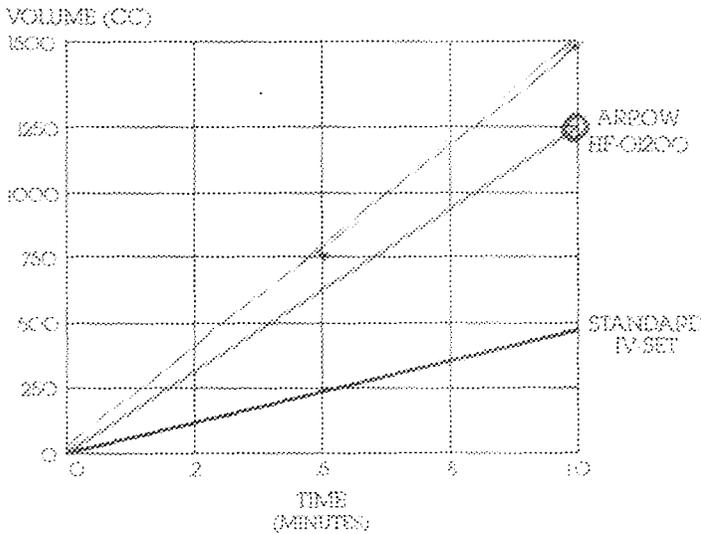
FLOW RATES-ISOTONIC SALINE
(GRAVITY INFUSED AT HEIGHT OF 46 CM)



FLOW RATES-PACKED CELLS
(DILUTED 2 TO 1 WITH SALINE)
PRESSURE INFUSED-300mm Hg



FLOW RATES-ISOTONIC SALINE
(PRESSURE INFUSED AT 300mmHg)



ARROW HIGH-FLOW™ FLUID ADMINISTRATION SET

This Arrow product offers significantly higher flow rates than previously available fluid administration sets. When used in conjunction with the Arrow 8.5 FR I.D. Emergency Infusion Device (E.I.D.) Catheter, EI-04080, or Trauma Kit, AK-05801, maximum fluid flow is attainable.

The Arrow High-Flow™ Fluid Administration Set offers duct spikes for uninterrupted infusion. Integral pinch-off clamps and other features afford many infusion options.

An Extension Set adds versatility by offering an additional injection port, a remote point for making connections, and greater distance between connection point and catheter insertion site for reduced risk of contamination.

* Trademark Medex, Inc.

Please refer to product package insert for cautions, indications, contraindications, and instructions for use.

Targeting your clinical needs
and cost realities.

ARROW

INTERNATIONAL, INC

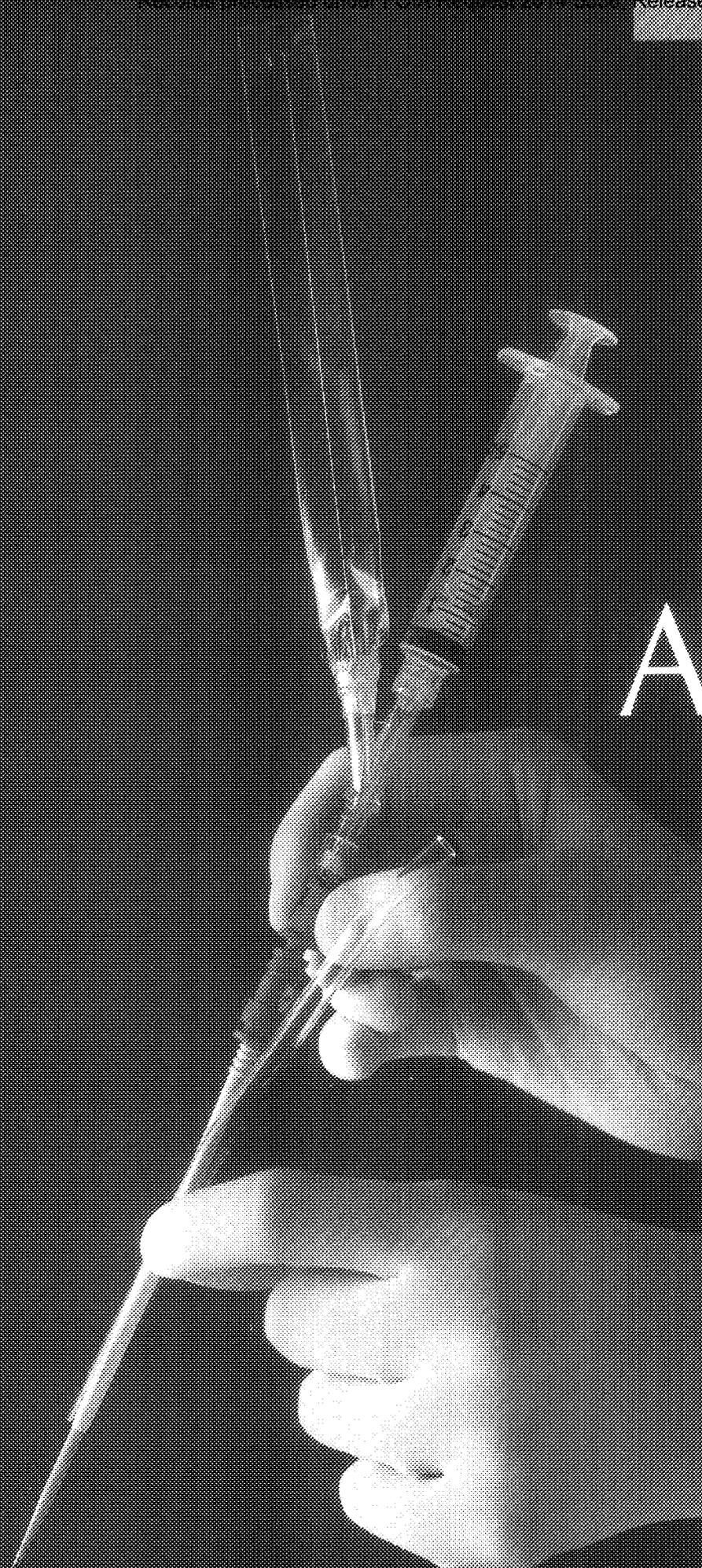
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In Pa. 800 628-8327
Fax: 215 374-5360

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Arrow International Inc (Europe)
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1360 A H Weesp, The Netherlands
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or in Toronto 416 890-0173

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2-8-3 Lidabashi
Chiyodaku
Tokyo 102
Phone: 011-813-222-5496
Fax: 011-813-222-5396



Arrow
Emergency
Fluid
Resuscitation
Devices

ARROW

Winning
the race
against time.

Arrow EID Catheters

Flow Rate Comparisons

Administration Tubing:
Abbott Non-Vented Blood Y-Type Set

Height of IV Bag: 75"

Catheter Height: 37"

Total Flow Distance: 48"

All volumes administered: 1000cc normal saline

Arrow: 8.5 fr. I.D. x 3 1/2"

	#1	#2	#3	Avg.
Gravity	3:15	3:20	3:17	3:17
Normal saline in pressure bag @ 300mm Hg	2:17	2:15	2:12	2:15

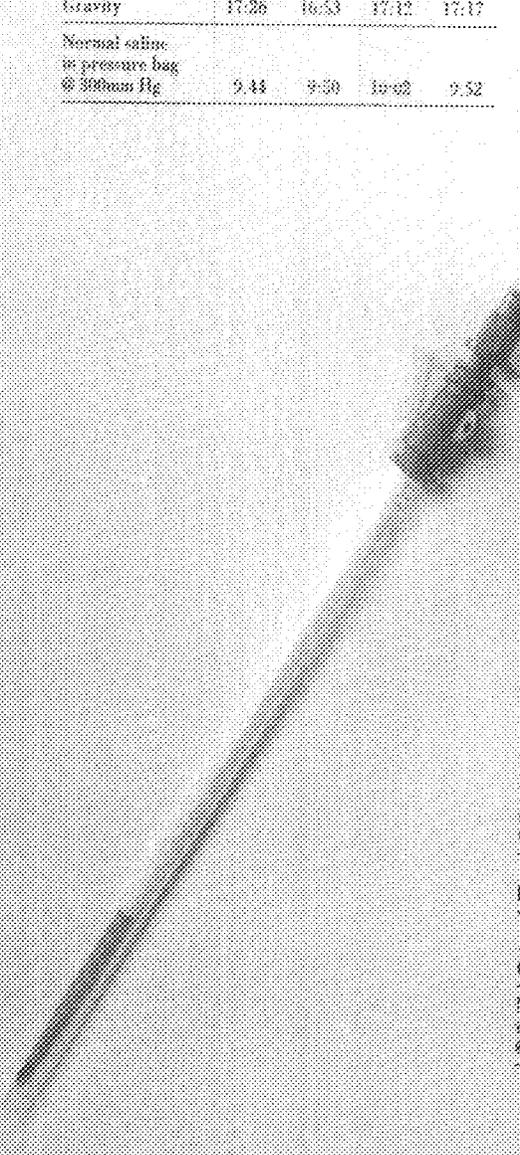
Time (minutes and seconds to administer 1000cc)

Blood Administration Set without catheter

	#1	#2	#3	Avg.
Gravity	4:18	4:20	4:15	4:17
Normal saline in pressure bag @ 300mm Hg	3:16	2:11	3:14	3:14

Deseret: 16 Ga. x 12" (IntraCath®)

	#1	#2	#3	Avg.
Gravity	17:26	16:53	17:12	17:17
Normal saline in pressure bag @ 300mm Hg	9:44	9:50	10:02	9:52



Cardix: 8 fr. x 4"

	#1	#2	#3	Avg.
Gravity	7:30	7:35	7:36	7:34
Normal saline in pressure bag @ 300mm Hg	4:31	4:50	4:40	4:40

Time (minutes and seconds to administer 1000cc)

Accuguide®: 16 Ga. x 8"

	#1	#2	#3	Avg.
Gravity	16:44	16:52	16:53	16:50
Normal saline in pressure bag @ 300mm Hg	9:27	9:19	9:29	9:25

Deseret Angio-Guide®: 14 Ga. x 6"

	#1	#2	#3	Avg.
Gravity	6:25	6:27	6:26	6:24
Normal saline in pressure bag @ 300mm Hg	3:38	3:40	3:37	3:38

The Arrow EID catheter improves emergency fluid resuscitation with higher flow rates and the fastest wire-guide insertion technique.

Rapid central venous catheterization for infusion of blood or other fluids in the emergency room, can mean life or death to severely hypovolemic patients.

Faster flow rate.

The Arrow EID percutaneously introduced catheter, in comparative studies shown at left,* has demonstrated a flow rate more than four times faster than traditional 16 Ga. through the needle catheters.

Here's why...

The Arrow EID utilizes a short bevel 17 Ga. thin-wall introducer needle, tapered dilator, and 8.5 Fr. I.D. Arrow-Flex™ Sheath. Because it's a sheath-over-dilator-over-needle system, the inside diameter of the EID is significantly larger than through-the-needle catheter or traditional catheter-over-needle designs. Therefore, the Arrow EID can provide greatly enhanced flow rates.

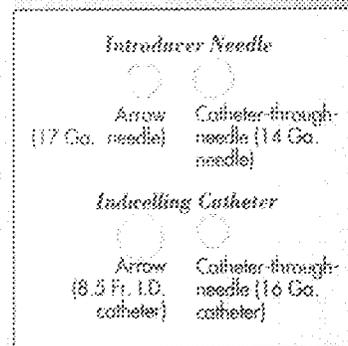
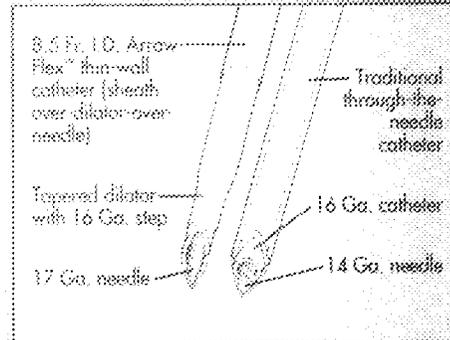
The Arrow EID also offers a viable alternative to cut-downs, with less trauma and risk of infection.

Features and Benefits

The Arrow EID system is engineered to provide wire-guide safety and convenience in use. Special features include:

*#11 blade scalpel...used for skin nicks...allows ease of introduction of a large-bore catheter.

- * Peel-away catheter/needle guard... easy to remove... helps protect against contamination during insertion.
- * Aspiration syringe for blood flashback... offers proof of accurate placement in vein.
- * Arrow spring-wire guide with soft "J" tip... provides ease of advancement and accurate placement in any central vein.
- * Arrow-Flex™ thin-wall catheter allows flexing up to a 90° angle in any direction... maintains patency without kinking... eliminates flow interruption. It can be subsequently used with the Arrow system of products for the introduction of PA and CVP catheters.
- * Sheath-over-dilator-over-needle system... allows safer introduction of large bore catheter by dilation... risk of catheter shearing by needle bevel edge is eliminated.



Product No.	Contents (10 units per case)
EI-04000	One 8.5 Fr. x 3 1/4" (8.90cm) Radiopaque Arrow-Flex™ Sheath Dilator Assembly over 17 Ga. Needle with integral .035" (.89 mm) dia. "J" tip Spring-Wire Guide and attached See Syringe
	One Disposable Scalpel (#11 blade)

* Studies available on request. Arrowguide is a registered trademark of Becton Medical, Inc. IntroCath and Angio-Guide are registered trademarks of Deseret Pharmaceutical Company, Inc.

Arrow Peripheral EID™ Catheters

When you need high volume fluid infusion quickly and don't want to incur the risks of inserting a central line, use the Arrow Peripheral Emergency Infusion Device.

It turns a two-stage technique into one easy step. By combining a 20 Ga. "search" needle device with a large-bore 6-French (I.D.) catheter/sheath and integral spring-wire guide, Arrow has found a way to speed up the initial phase of peripheral high-volume fluid infusion. It's a critical innovation in emergency procedures.

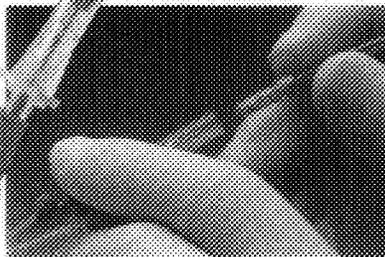
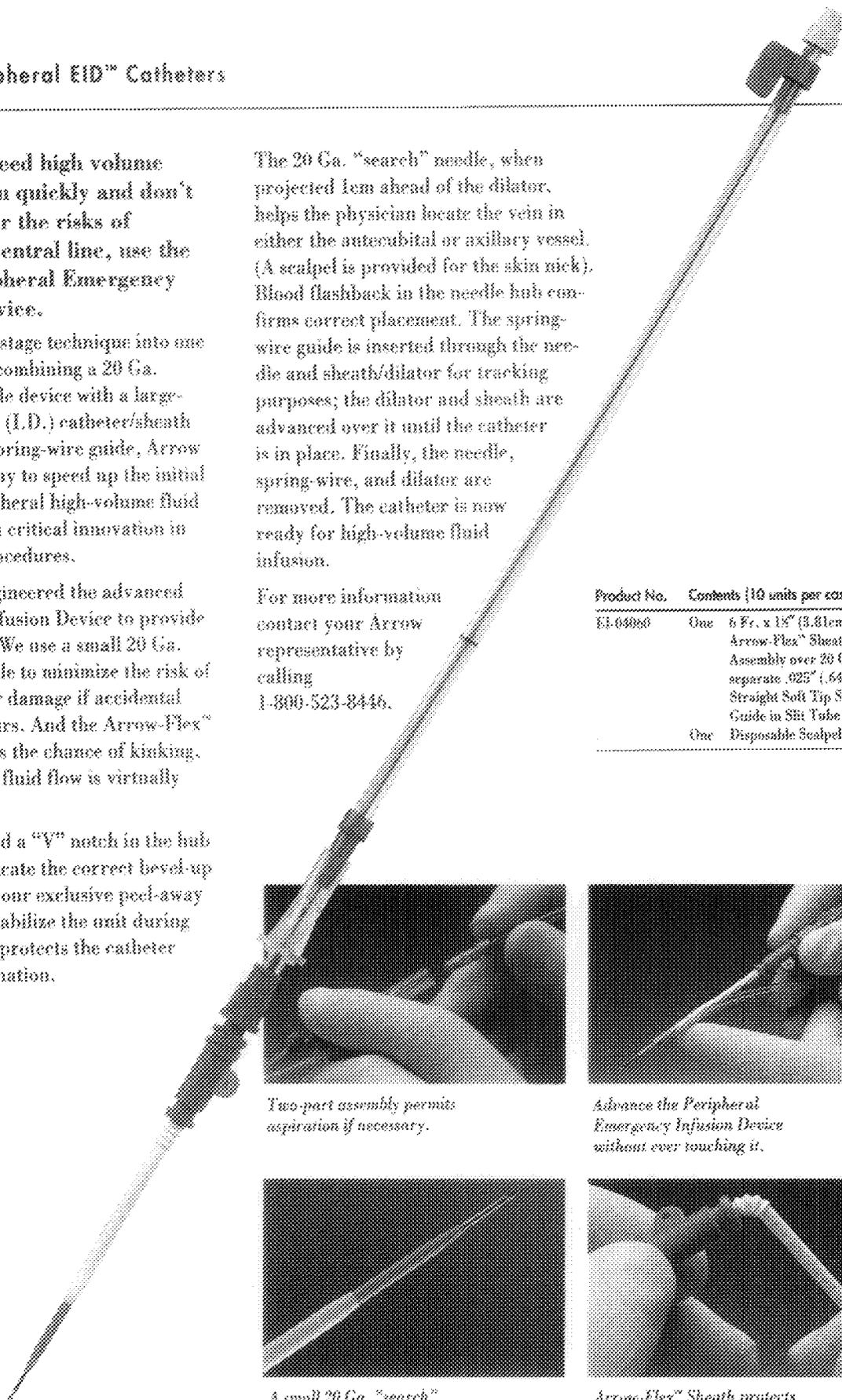
Arrow has engineered the advanced Emergency Infusion Device to provide added safety. We use a small 20 Ga. "search" needle to minimize the risk of neurovascular damage if accidental puncture occurs. And the Arrow-Flex™ sheath reduces the chance of kinking, so continuous fluid flow is virtually guaranteed.

We also located a "V" notch in the hub to readily indicate the correct level-up position. And our exclusive peel-away guard helps stabilize the unit during insertion and protects the catheter from contamination.

The 20 Ga. "search" needle, when projected 1cm ahead of the dilator, helps the physician locate the vein in either the antecubital or axillary vessel. (A scalpel is provided for the skin nick). Blood flashback in the needle hub confirms correct placement. The spring-wire guide is inserted through the needle and sheath/dilator for tracking purposes; the dilator and sheath are advanced over it until the catheter is in place. Finally, the needle, spring-wire, and dilator are removed. The catheter is now ready for high-volume fluid infusion.

For more information contact your Arrow representative by calling 1-800-523-8446.

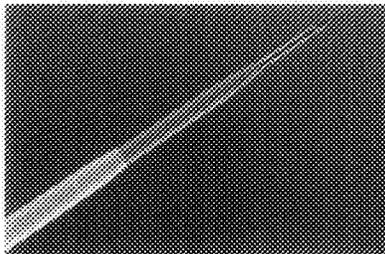
Product No.	Contents (10 units per case)
EL-04060	One 6 Fr. x 15" (3.81cm) Radiopaque Arrow-Flex™ Sheath Dilator Assembly over 20 Ga. Needle with separate .025" (.64mm) dia. Straight Soft Tip Spring-Wire Guide in Silt Tube Holder
	One Disposable Scalpel (#11 Blade)



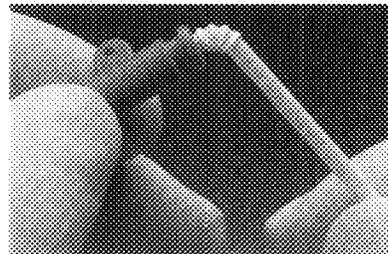
Two-part assembly permits aspiration if necessary.



Advance the Peripheral Emergency Infusion Device without ever touching it.



A small 20 Ga. "search" needle minimizes risk of neurovascular damage.



Arrow-Flex™ Sheath protects against kinking.

Arrow High-Flow Fluid Administration Set

Now deliver more fluid per second with the Arrow High-Flow Fluid Administration Set.

In trauma cases, in E.D. and O.R. situations—whenever life hangs in the balance—you need the highest possible infusion rates, plus easy placement and precise control.

The Arrow 8.5 Fr. minimum I.D. line delivers flow rates of up to 1615 ml/min., as much as 300 percent higher than a standard infusion line.*

In the Arrow High-Flow Blood Line, many features work together to help you as no ordinary blood line can, when and where seconds count.

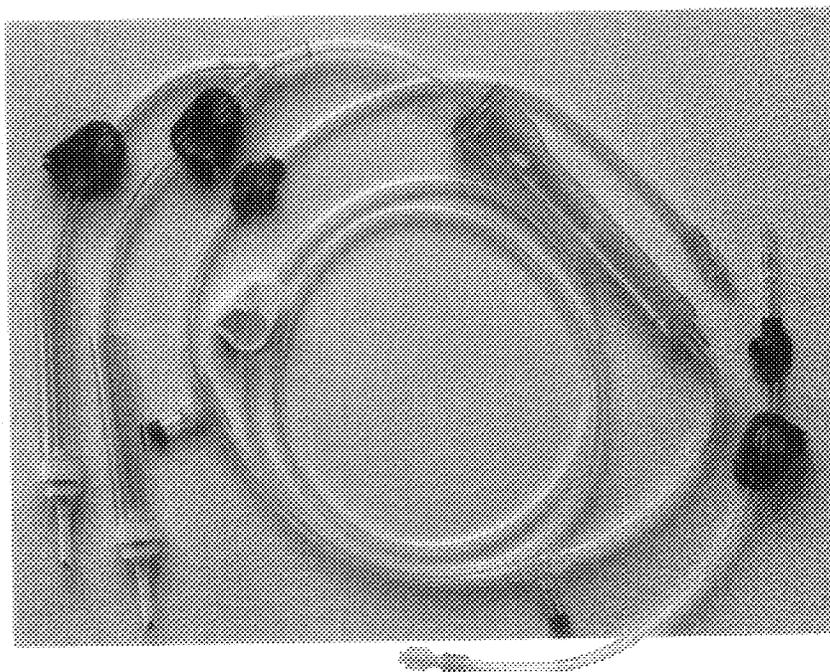
High-Flow extension set adds versatility.

A 12 in. (30cm) extension line provides for safer technique while changing lines. This line also offers an additional injection port, a remote port for making connections such as a replacement blood line, and a pinch-off clamp to minimize blood loss or air embolism complications. The extension line also reduces the risk of contamination by distancing the connection point from the catheter insertion site.

Variety of treatment options.

- * All hubs of both the extension line and infusion line are Luer Lock to minimize disconnect problems.
- * Dual spikes give you two fluid sources you can alternate, for uninterrupted infusion.
- * Integral pinch-off clamps are provided on the line and the extension set.
- * When used with extension set, a total of two integral injection ports plus a Luer Lock "T" injection site give several treatment options.

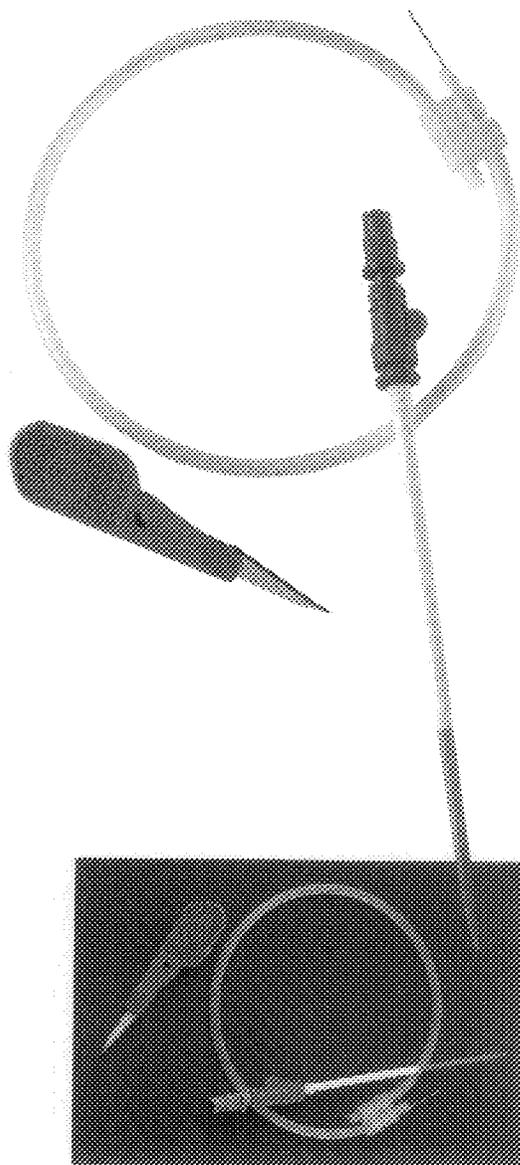
Contact your Arrow representative for more information by calling toll-free 1-800-523-8446.



Product No.	Contents (10 sets per case)
HF 01200	One Two-Spike Large Bore (8.5 Fr. min. I.D.) Fluid Administration Set with Blood Filter
	One Extension Set

* These rates are achieved with saline and a pressure infuser of 300mm Hg. The Arrow 8.5 Fr. I.D. Emergency Infusion Device Catheter or trauma kit are recommended for best results.

Arrow RIC™ (Rapid Infusion Catheter)



Far faster, safer large-bore venous access with the Arrow RIC™ (Rapid Infusion Catheter).

The concept for the large-bore Arrow RIC™ catheter system is simplicity itself.

Any time a 20 gauge or larger peripheral IV catheter is already in place in a suitably sized vein, you can start high-volume fluid resuscitation or infusion sooner with an almost instantaneous exchange of the existing catheter for the Arrow Rapid Infusion Catheter 7 or 8.5 Fr. (inside diameter) catheter/sheath over dilator.

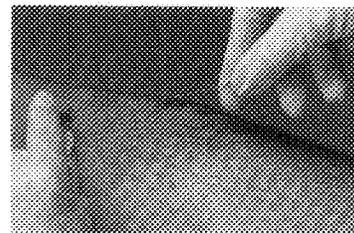
Now you can deliver maximum fluid flow peripherally to hypovolemic patients—within seconds—without the risk or difficulty of a second venipuncture. And just as important, the need for central venous catheterization and its inherent risks can be reduced.

In a study,¹ successful placement of the Arrow Rapid Infusion Catheter was made in an average time of 97.5 seconds—with a procedure time as low as 20 seconds in one instance.

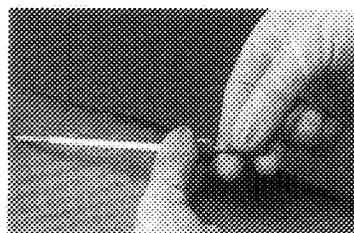
All Arrow RIC™ sets include a sheath/dilator with Arrow-Flex™ spring-wire with straight soft tip at both ends, and #11 blade scalpel.

Ask your Arrow International representative for details, including suggested procedures for use, on the lifesaving potential of the Rapid Infusion Catheter, Product No. RC-09700 or RC-09850 or call toll-free 1-800-523-8446.

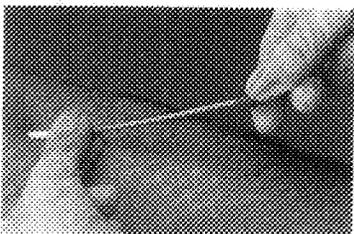
Product No.	Contents (25 sets per case)
RC-09700	One 7 Fr. (Nominal Catheter I.D.) x 2" (5.08cm) FEP Radiopaque Arrow-Flex™ Catheter/Dilator Assembly
	One .025" (64mm) dia. x 13 1/2" (33.3cm) "High-Strength" Spring-Wire Guide (straight soft tip both ends)
	One Disposable Scalpel (#11 Blade)
RC-09850	One 8.5 Fr. (Nominal Catheter I.D.) x 2 1/2" (6.35cm) FEP Radiopaque Arrow-Flex™ Catheter/Dilator Assembly
	One .025" (64mm) dia. x 13 1/2" (33.3cm) "High-Strength" Spring-Wire Guide (straight soft tip both ends)
	One Disposable Scalpel (#11 Blade)



1. After antiseptic swab of venipuncture site, disconnect existing IV tubing. Insert spring-wire into previously placed catheter, and remove catheter over wire.



2. After incising skin with #11 blade approximately 5mm for easier insertion, place Arrow sheath/dilator over spring-wire, and introduce it into the vein.



3. Remove spring-wire and dilator, leaving sheath in vein.



4. Connect IV tubing. For highest flow rate, use the Arrow High Flow Administration Set¹ (Product No. HF-01200 or HF-01201).

¹ Cavallaro, D.L.; Rossmurgy, A.S.; Machin, J.P., and Brodowski, S.H.; University of South Florida College of Medicine. Unpublished study on file at Arrow International, Inc.

Arrow Trauma Kit

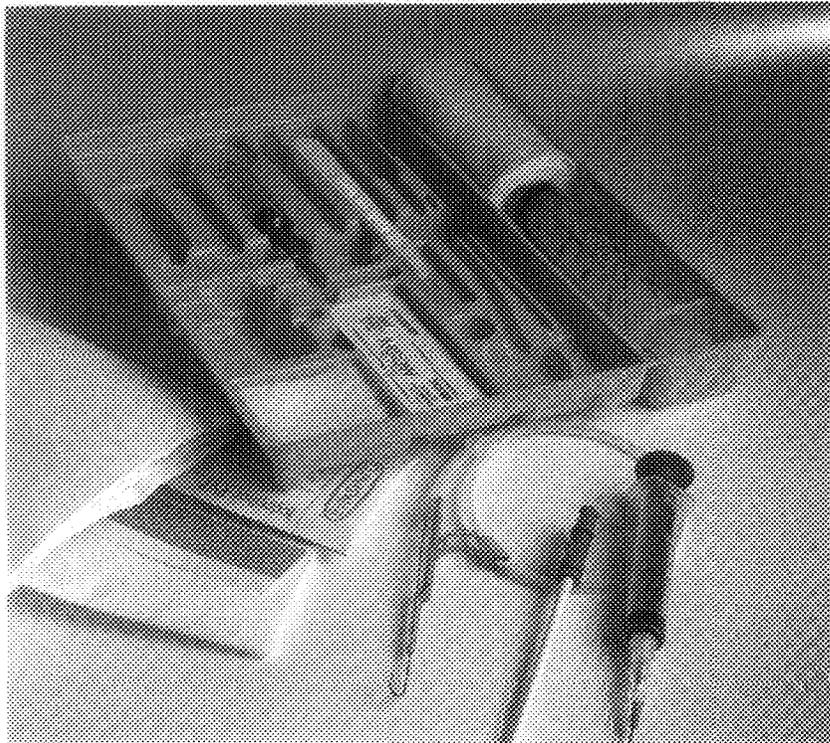
No other product on the market can match the procedure-enhancing benefits of the Arrow Trauma Kit (Product No. AK-05801).

This Percutaneous Sheath Introducer Kit has been designed specifically for E.D. situations. It minimizes risk of complications and is procedurally complete.

Because time is critical, the first advantage is easier spring-wire guide placement. By using a simplified Seldinger technique to place the sheath, made possible by the use of the patented Arrow® Raulerson Syringe, Arrow Advancer,™ and the special .035" (.89mm) x 17 1/2" (45cm) spring-wire guide with markings at 10cm, 20cm, and 30cm, you can place a spring-wire guide in fewer steps.

The Arrow® Raulerson Syringe is designed with a unique hollow plunger/barrel containing a patented valving system. So the spring-wire guide can be inserted directly into the plunger/barrel, through the introducer needle, and into the vein. The syringe barrel doubles as a blood containment device, reducing the risk of operator exposure to blood, as recommended by the CDC Universal Precautions. There's less trauma, less contamination risk, and less chance of spring-wire guide misplacement. And of most importance, there's virtually no potential for air embolism, during spring-wire guide introduction.

The advantages continue with the 8.5 Fr. I.D. Arrow-Flex™ catheter/sheath. It has the inside diameter necessary to maintain the high flow rates desirable in emergency situations. And the Arrow-Flex™ feature allows the sheath to bend up to 90° at the junction



hub to help prevent kinking and the resultant reduction in flow rates.

All the features mentioned above, and more, are packaged sterile in one complete kit.

Product No.	Contents (10 kits per case)
AK-05801	One 8.5 Fr. Radiopaque Arrow-Flex™ Catheter Sheath/Dilator Assembly
	One 0.35" (.89mm) dia. x 17 1/2" (45cm) Dual Purpose Marked Spring Wire Guide (straight soft tip on one end— "J" tip on other) with Arrow Advancer™
	One 30cc Syringe
	One 5cc Arrow® Raulerson Syringe
	One Pressure Transduction Probe
	One 5cc Syringe
	One 22 Ga. x 1 1/2" (3.81cm) Needle
	One 18 Ga. x 2 1/2" (6.35cm) Introducer Needle
	One Disposable Scalpel (#11 Blade)
	One Straight Silk Suture
	Three Povidone-Iodine Swabsticks
	Two 2" x 2" Gauze Pads
	Five 4" x 4" Gauze Pads
	One Small Sterile Dressing
	One Frustrated Drape
	One CSB Wrap

18

For information regarding distribution in your area contact:



Arrow Emergency Fluid Resuscitation Devices

Product No.	Description	Per Case
Kits		
AK-05801	Arrow Trauma Kit containing 8.5 Fr. Percutaneous Trauma Catheter/Sheath	10
AK-09000	Arrow Peritoneal Lavage Kit (Not featured) containing 8 Fr. x 8 1/2" (21.0cm) Lavage Catheter	10
Sets		
RC-09700	Arrow Rapid Infusion Catheter Exchange Set containing 7 Fr. Percutaneous Catheter/Dilator Assembly	25
RC-09850	Arrow Rapid Infusion Catheter Exchange Set containing 8.5 Fr. Percutaneous Catheter/Dilator Assembly	25
RF-01200	Arrow High Flow Fluid Administration Set with Blood Filter and Extension Set	10
Units		
EI-04060	Arrow Peripheral Emergency Infusion Device containing 6 Fr. Sheath/Dilator Assembly for Emergency Fluid Resuscitation	10
EI-04080	Arrow Emergency Infusion Device-E.I.D.™ containing 8.5 Fr. Sheath/Dilator Assembly for Emergency Fluid Resuscitation	10

Technique developed in cooperation with Daniel L. Corbridge, University of South Florida College of Medicine.

The Arrow® Henderson Spring Wire Introduce Syringe is a joint development of J. Donald Henderson, M.D., and Arrow International, Inc., U.S. Patent Number 4,813,938. Other U.S. and foreign patents pending.

Caution: The color of blood aspirated is not always a reliable indicator of venous access. In cooperation with the Arrow® Henderson Syringe use the introduction probe, included in the kit, to verify correct vessel placement via a waveform obtained by a catheterized pressure transducer.†

† J. Jaber, DR, S. Schwartz, A.J. Greenhaw, DE, Unpublished, NY. Hagan, M. Inferior jugular vein cannulation: recognition of arterial puncture and prevention of use of the external jugular route. *Anesthesiology* 35:3-355, Oct., 1987.

Note: If hemodynamic monitoring equipment is not available to permit monitoring a central venous waveform, disconnect the syringe from the needle and check for pulsatile flow. Pulsatile flow is usually a direct indicator of inadvertent arterial puncture.

Caution: U.S. Federal law limits this device to sale by or on order of a physician. Contents of unopened, undrugged packages are sterile. Contains medication. Disposable. Refer to package insert for current warnings, precautions, and instructions for use.

Contact Arrow International, Inc. for reference information on the above.

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A-9 8/93 20M



United States

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Reading, PA 19605
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Call toll free 800-323-8448
Order only toll free for: 800-343-2915
Fax: 215-378-3199

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Arrow Medical Products Ltd.
150 Johnson Road East, Unit #23
Mississauga, Ontario L4Z 1S9
Call toll free 800-387-7817
or in Toronto 416-890-0173

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Fax: (081) 3122 40384

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Klein 2054
Republic of South Africa
Phone: (31) 444 0950/172
Fax: (31) 444 0519

2

Multidex



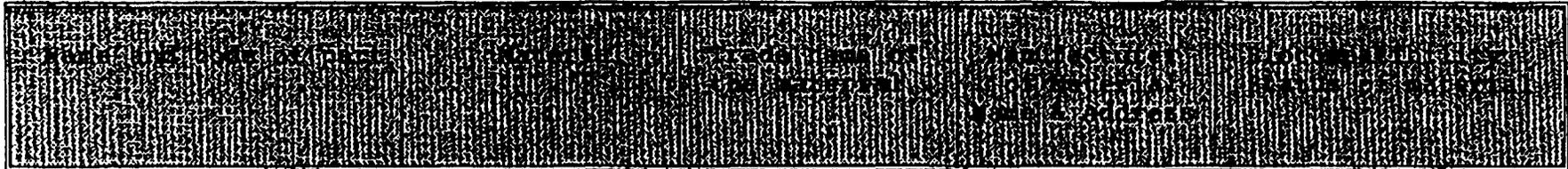
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80

ATTACHMENT 2

8/14

COMPONENT MATERIAL INFORMATION FOR REGISTRATION PURPOSES

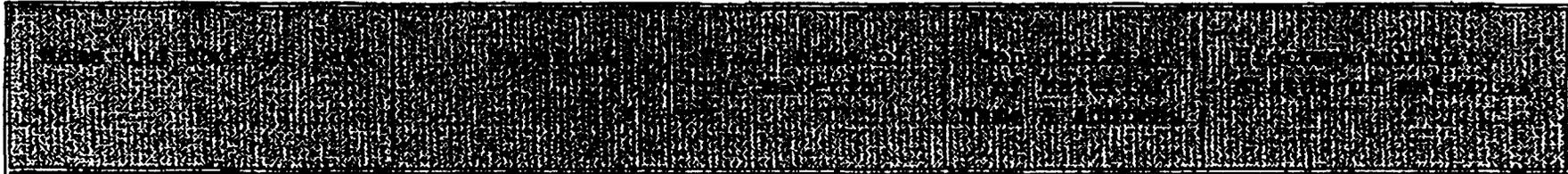


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47
p8

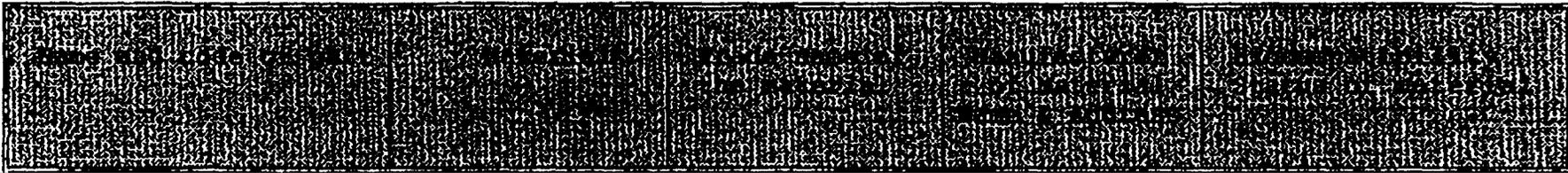
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(b) (4)



8/1



(b) (4)



6/19

3

MultiDex[™]

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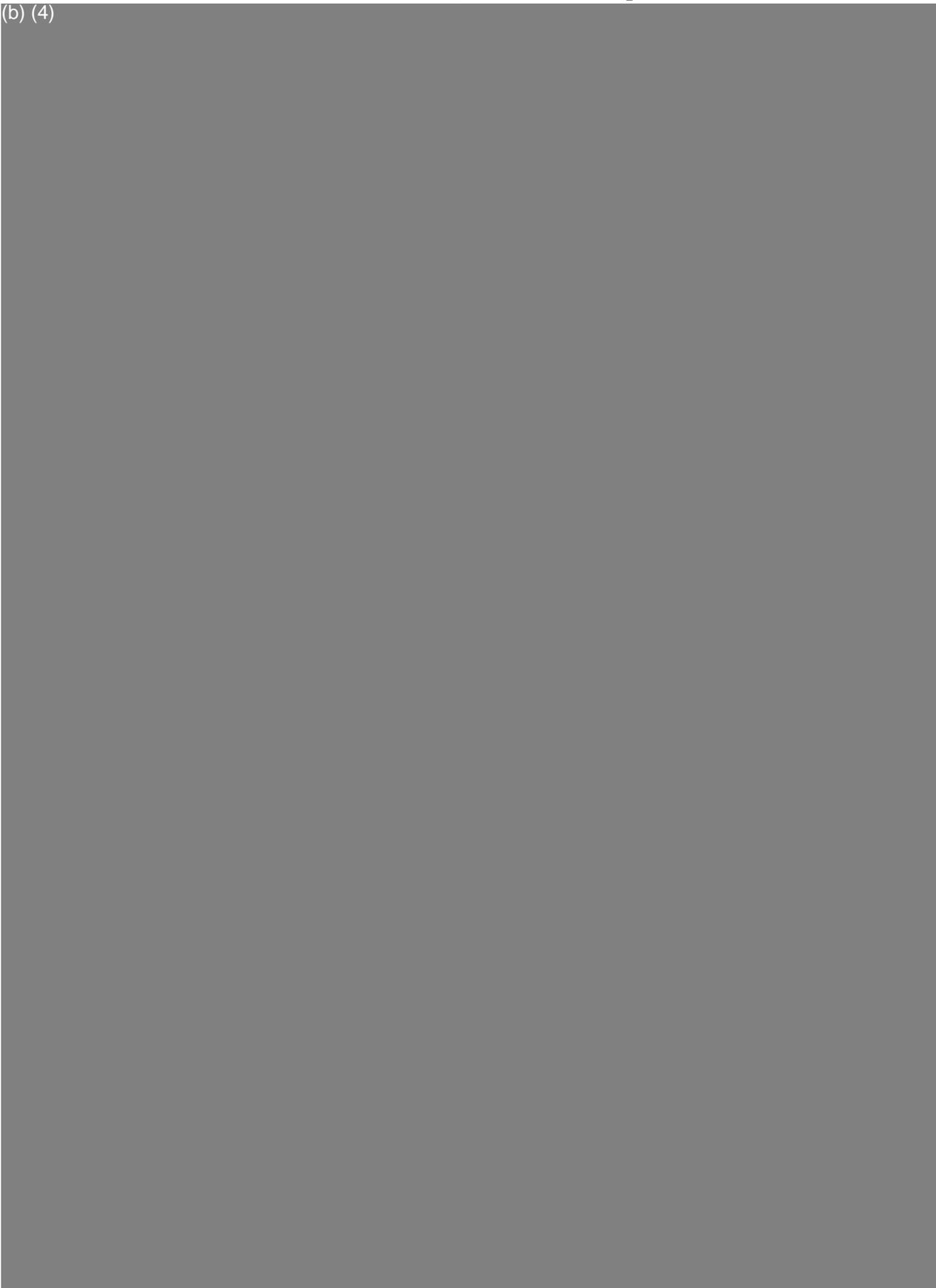
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ATTACHMENT 3

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Product Qualification Report

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TEST REQUEST

(b) (4)



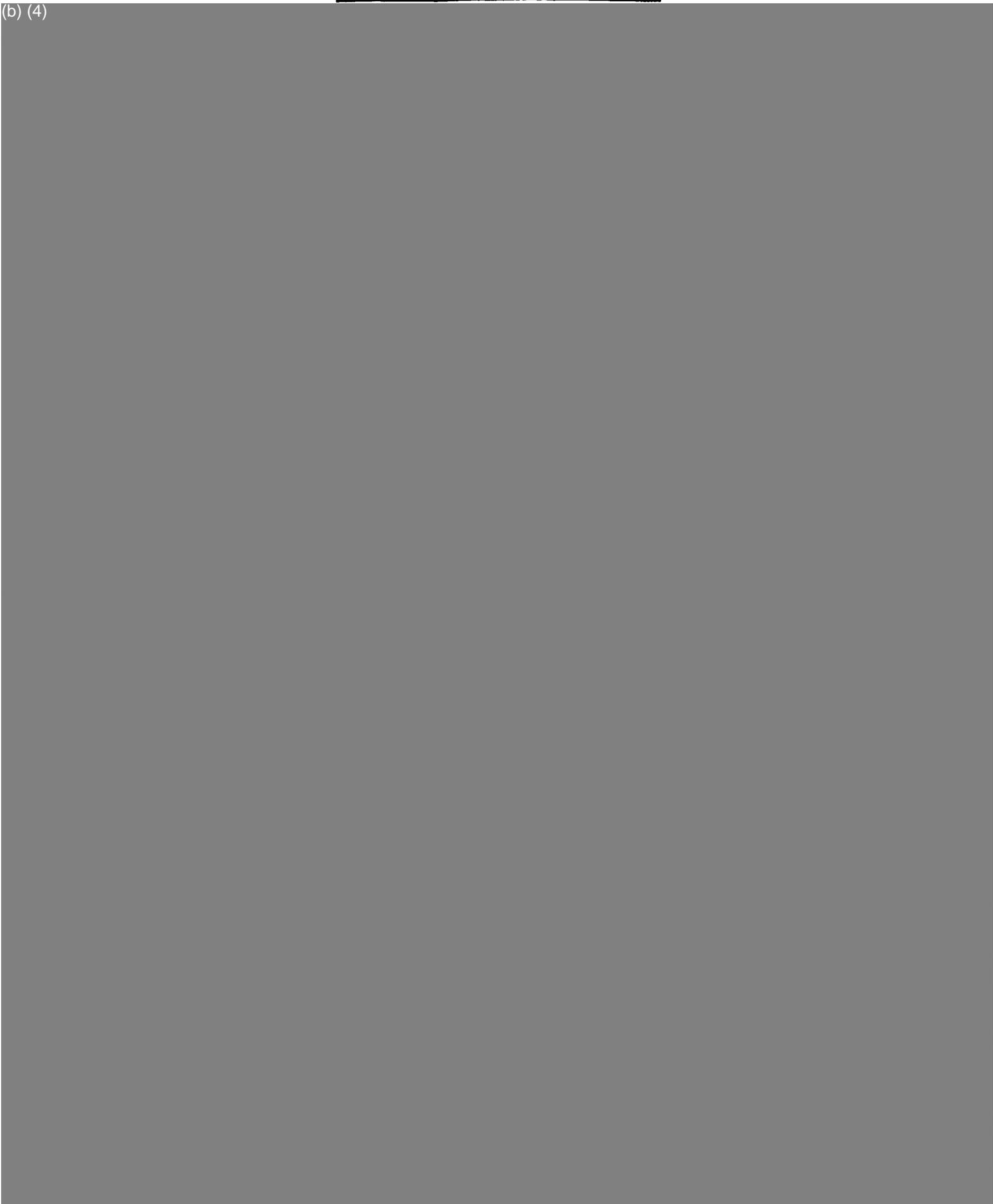
TEST REPORT

(b) (4)



TEST REQUEST

(b) (4)



DATE: 1/14/87 (NEW)

FLOW RATE RESULTS

(b) (4)



DATE: 1/14/87 (New)

FLOW RATE TEST

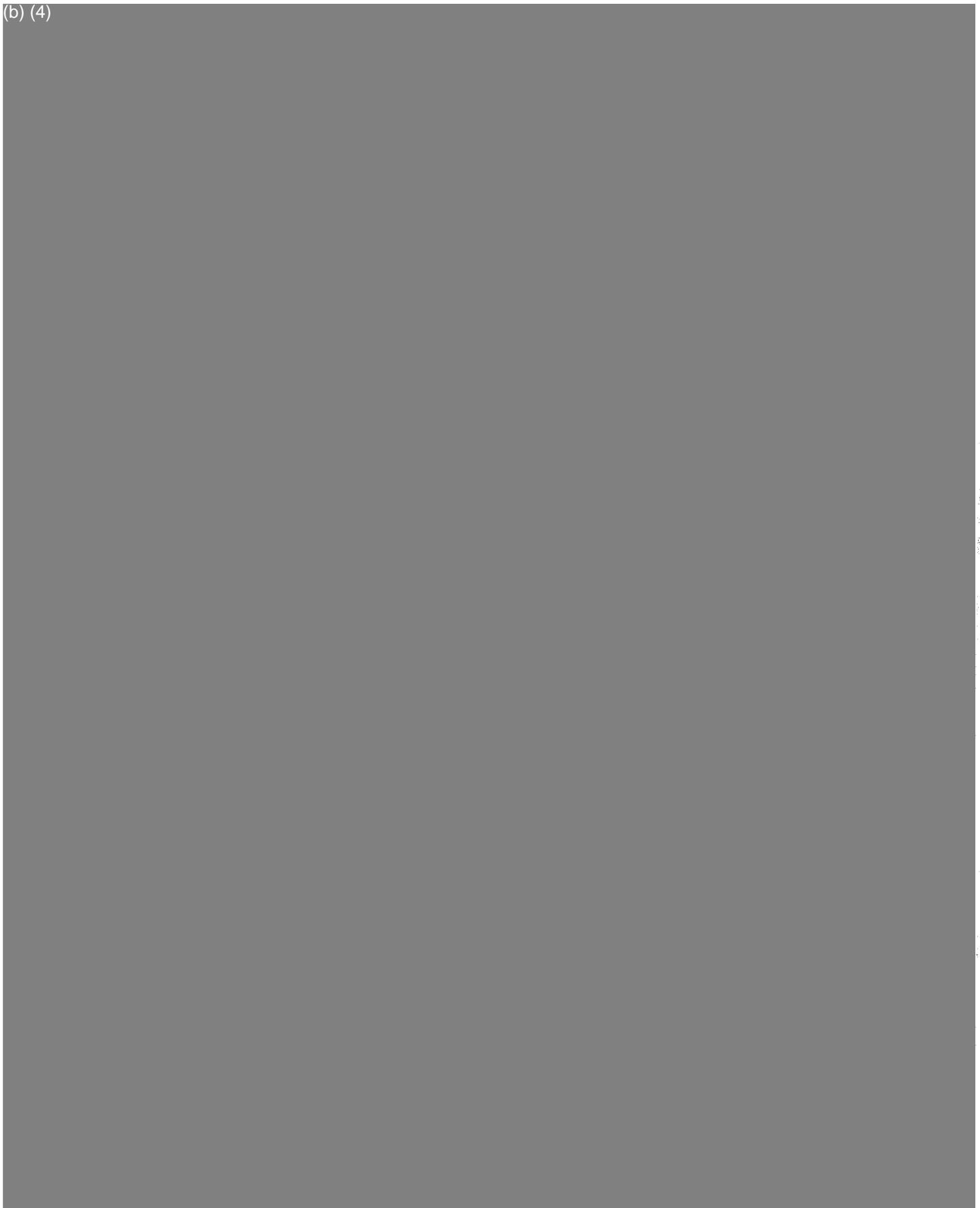
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DATE: 1/14/87 (NEW)

FLOW RATE RESULTS

(b) (4)



DATE: 1/14/87 (New)

FLOW RATE TEST

(b) (4)



4

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103



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ATTACHMENT 4

104
35

BIOLOGICAL TESTS (CONTRACT LAB)

(b) (4)



BIOLOGICAL/PHYSICAL TEST CODE NUMBERS

(b) (4)



106
37

Arrow

International, Inc

*P.O. Box 12888 3000 Bernville Road
Reading, PA 19612 Reading, PA 19605*

*(610) 378-0131
FAX (610) 478-3188
February 9, 1994*

(b) (4)



Thank you for your attention.

Sincerely,



Ronald P. Citron
Senior Research Scientist

109/40

Arrow

International, Inc

*P.O. Box 12888 3000 Bernville Road
Reading, PA 19612 Reading, PA 19605*

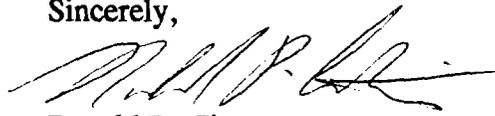
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FAX (610) 478-3188
February 14, 1994*

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Thank you for your help.

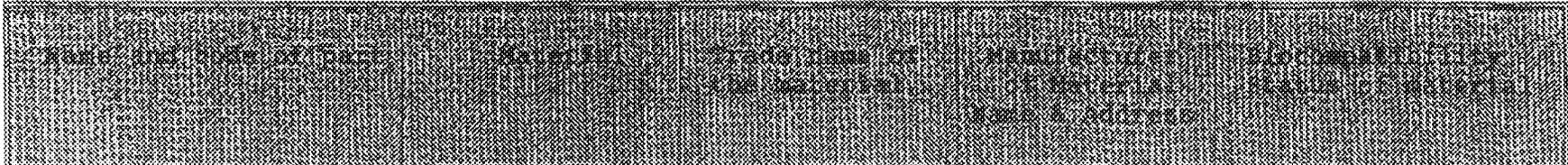
Sincerely,



**Ronald P. Citron
Senior Research Scientist**

110
41

COMPONENT MATERIAL INFORMATION FOR REGISTRATION PURPOSES

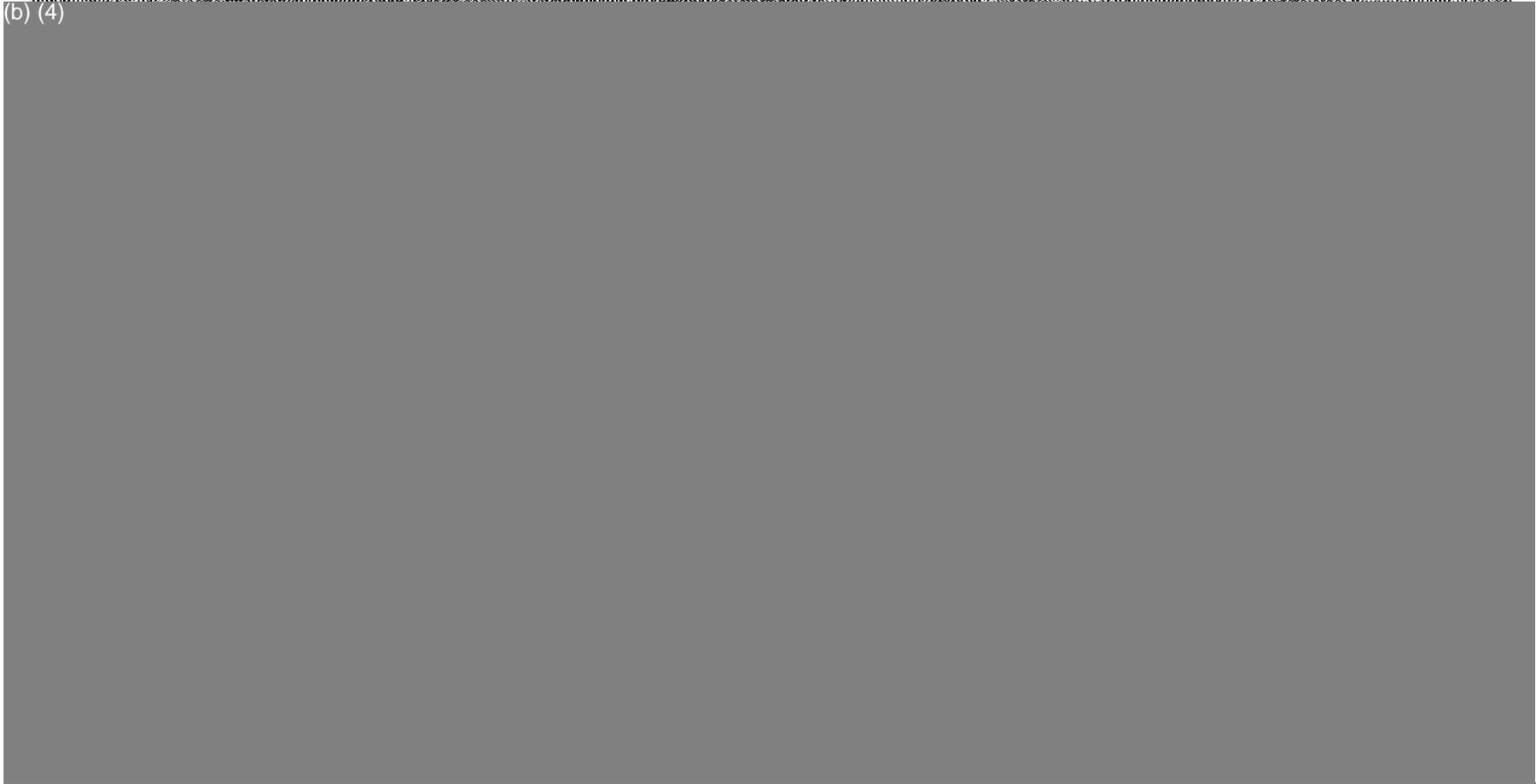
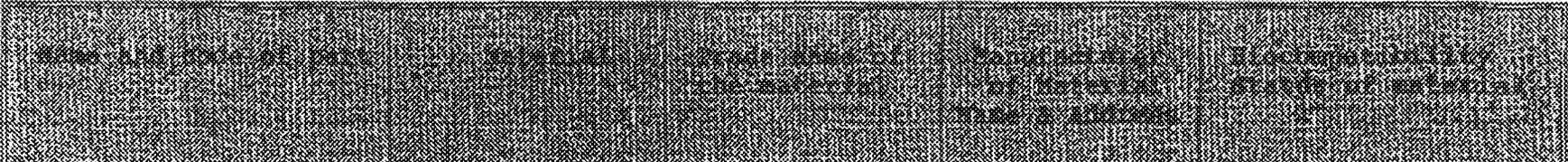


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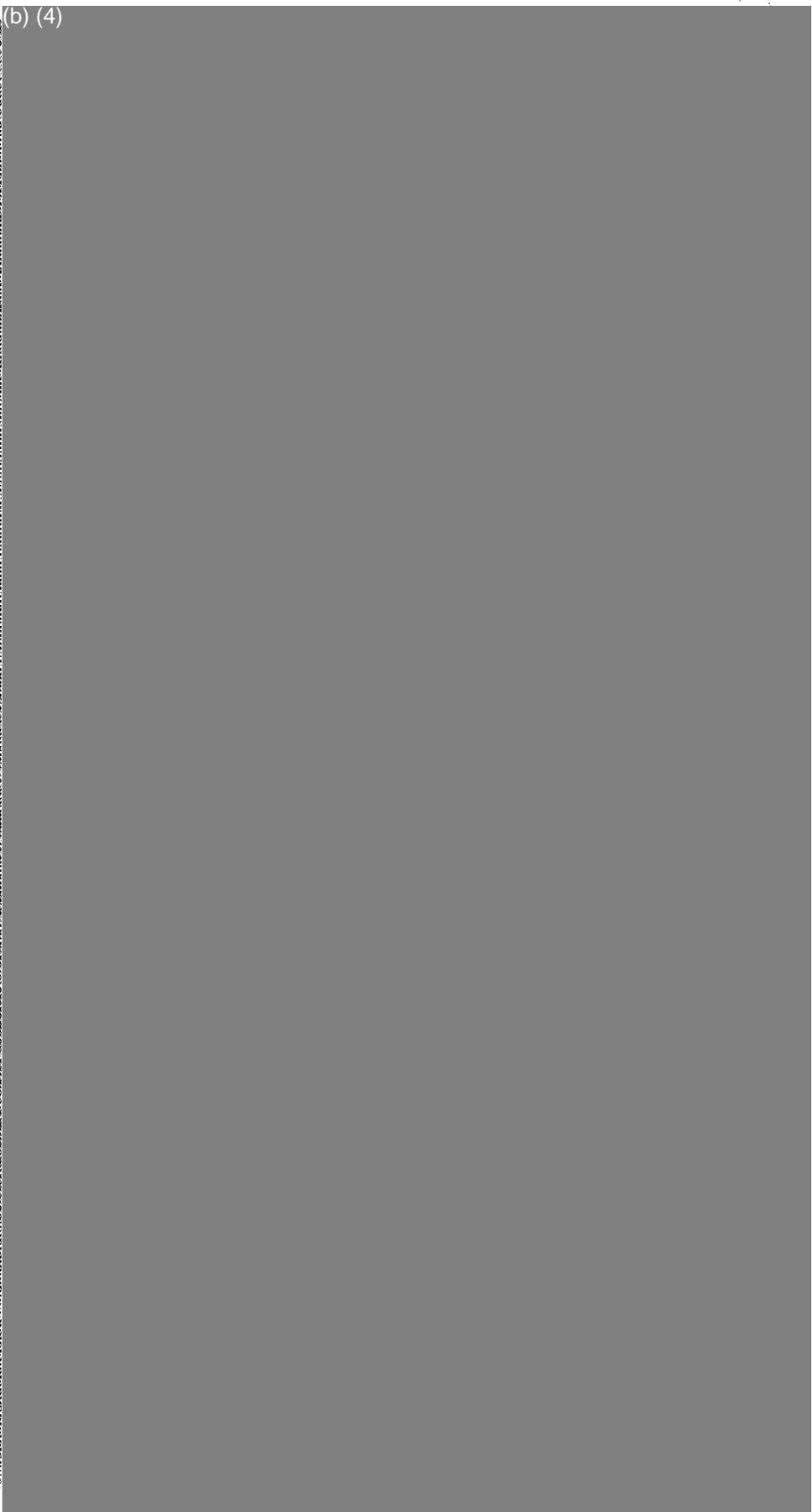
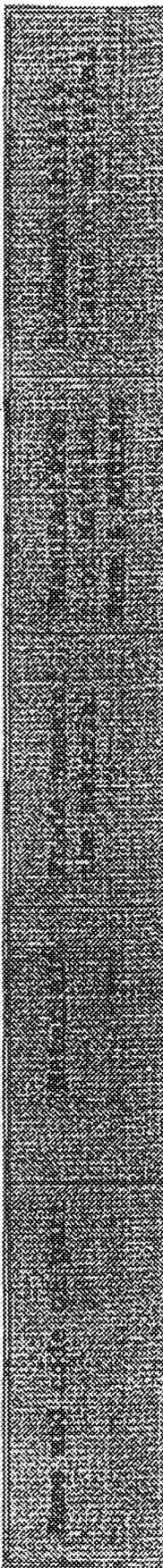
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47



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FAX 419•666•2954

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P.O. NO. E-53836

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D.O.M. March
1992.

READING, PA 19612
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CYTOTOXICITY - AGAROSE OVERLAY. SOLID

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HEMOLYSIS TEST *IN VITRO*

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**CERTIFICATE OF COMPLIANCE
USP BIOLOGICAL TESTS
CLASSIFICATION V**

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Page 1 of 2

**ACUTE SYSTEMIC TOXICITY - T12
(CURRENT USP)**

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-2-

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Test Article: "Pellets"

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Page 1 of 2

**INTRACUTANEOUS TOXICITY - T13
(CURRENT USP)**

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Test Article: "Pellets"

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STUDY TITLE:

AMES MUTAGENICITY STUDY
OF A SALINE EXTRACT

TEST ARTICLE:

"PELLETS"

IDENTIFICATION NO.:

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121
56

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STUDY TITLE:

DELAYED CONTACT SENSITIZATION STUDY

(A Maximization Method)

IN THE GUINEA PIG

(SALINE EXTRACT)

TEST ARTICLE:

"PELLETS"

IDENTIFICATION NO.:

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130
63

