USER: GRAY, ILKA K (ixg)

FOLDER: K896422 - 69 pages (FOI:10006595)

COMPANY: BURRON MEDICAL, INC. (BURRMEDI)

PRODUCT: PUMP, INFUSION (FRN)

SUMMARY: Product: BURRON AMBULATORY DRUG DELIVERY SYSTEM

DATE REQUESTED: Thu Oct 21 24:00:00 2010

DATE PRINTED: Fri Oct 22 11:13:26 2010

Note: Releasable Version

Table of Contents

FOLDER - INFUSION PUMP - 67 pages **1**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

MAY 9 1990

Ms. Peggy Keiffer
Regulatory Affairs Coordinator
Burron Medical, Inc.
824 Twelfth Avenue
Bethlehem, Pennsylvania 18018

Re: K896422
Burron Ambulatory Drug
Delivery System
Dated: October 31, 1989
Received: November 8, 1989
Regulatory Class: II

Dear Ms. Keiffer:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the act include requirements for annual registration, listing of devices, good manufacturing practices, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) 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. 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 the Radiation Control for Health and Safety Act of 1968 such as the requirement to submit an initial report prior to marketing radiation emitting devices, or other applicable Federal laws or regulations.

This letter immediately will allow you to begin marketing your device if you have met all other requirements described above. An FDA finding of substantial equivalence of your device to a pre-Amendment 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 on the labeling for your device, please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. 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,

Halyna Breslawec

Halyna P. Breslawec, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 5/8/90

From REVIEWER(S) - NAME(S) Mattan

Subject 510(k) NOTIFICATION K896422 /B

To THE RECORD

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

✓ (A) Is substantially equivalent to marketed devices. see memo

____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

____ (C) Requires more data.

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

Additional Comments:

The submitter requests under 21 CFR §807.95:

____ No Confidentiality

✓ Confidentiality for 90 days

____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

II 80 FRN

Additional Product Code(s) w/Panel (optional):

5/9/90

REVIEW: Acting Amalie C. Mattan (BRANCH CHIEF) 5/8/90 (DATE)

FINAL REVIEW: I Bernstein (DIVISION DIRECTOR) 5/9/90 (DATE)

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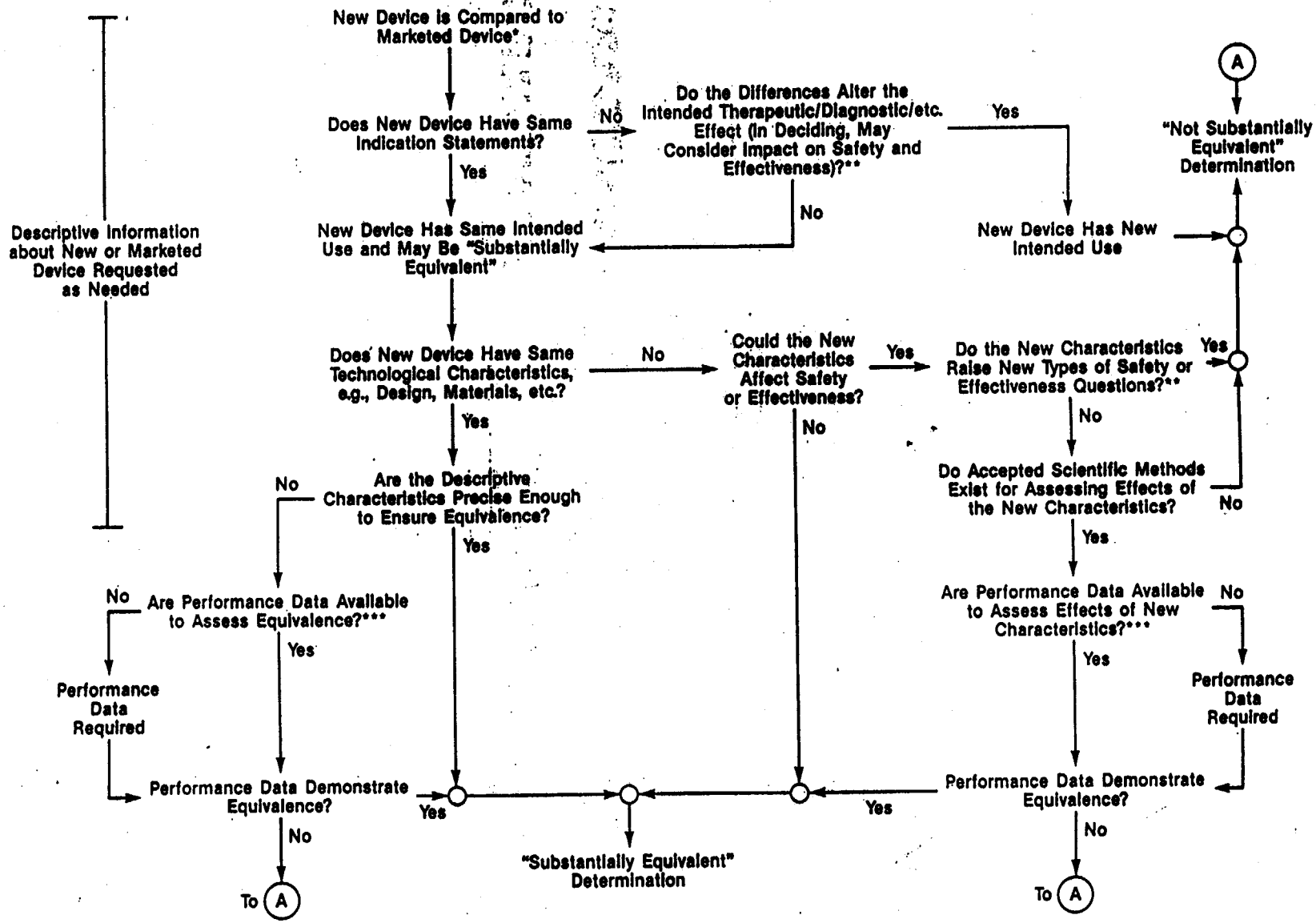
X 2

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.

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510(k) #: K896422

Generic Name: Infusion Pump

Panel: 80

Code: FRN

Class: II

Trade Name: Burron Ambulatory Drug Delivery System

Submitter: Burron Medical Inc.
Location: Bethlehem, PA
Contact(s): Peggy Keiffer
(215) 691-5400

ACM Date: 11/16/89

Intended Use: for continuous intravenous administration of medication

Materials: polyethylene, polycarbonate, Si rubber, polypropylene, natural rubber, styrene, stainless steel, polyurethane, PVC, paper, glass, ABS, acrylic copolymer, nylon

Sample: no

Labeled as Sterile: yes

Sterilization Method: (b)(4)

SAL: 10^{-48}

(b)(4)

(b)(4)

Pyrogen free: yes

Have the following been supplied?	**YES**	**NO**	**NA**
a)the sterilization cycle validation method	X	___	___
b)description of packaging to maintain device sterility	X	___	___
c)the method used to make a pyrogen free determination	LAL	___	___

SE Device: Healthtek's ADFuse Ambulatory IV Infusion System

Comments: This device is a lightweight, disposable device which uses a constant internal pressure to infuse medication at a fixed rate. When filled, the device operates with internal energy provided by a precision compression spring. The contents are delivered through a filter (when provided) and a controlled size orifice. The system is designed to deliver a max of 100ml of medication. It provides a continuous medication flow over the infusion period, at either 100ml/hr, 200ml/hr, or 2ml/hr +/-15%.

Recommendation: SE
Date: 05/08/90

Amalie C. Mattan

Amalie C. Mattan

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BURRON MEDICAL INC.

B. Braun of America Company • 824 Twelfth Avenue • Bethlehem, PA 18018

Telephone: (215) 691-5400
Telex: 6855207 BURRON BETM
Telefax: 215-691-2202

May 1, 1990

Ms Amalie Matten
FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
HFZ-420
1390 Piccard Drive
Rockville, Maryland 20850

Re: K896422 Burron Ambulatory Drug Delivery System
Additional Information

Dear Ms Matten:

Enclosed is the additional information requested by phone on April 26, 1990 for the 510k submission # K896422, Burron Ambulatory Drug Delivery System.

1. Provide a written statement certifying that all materials have met USP Class VI requirements.

   All materials used in this device meet or exceed the USP Class VI requirements.

2. Provide a written statement concerning the effects of freezing on the materials used in this device.

   Freezing has no detrimental affects on the integrity or performance of this device. Individual sub-assemblies, subjected to freezing, met or exceeded test performance standards. The completed device, subjected to freezing, met or exceeded test performance standards.

I trust this satisfies your requirements. If there are any questions about this information, please contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator
005-060

cc: W. Barrett
E. Brobst
R. Larson
K. Raines
T. Ronca

RETURN RECEIPT REQUESTED---CERTIFIED MAIL # P 333 734 872

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SERVICE TO THE MEDICAL PROFESSION AROUND THE WORLD

BURRON MEDICAL INC.

B. Braun of America Company • 824 Twelfth Avenue • Bethlehem, PA 18018

Telephone: (215) 691-5400
Telex: 6855207 BURRON BETM
Telefax: 215-691-2202

May 1, 1990

Ms Amalie Matten
FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
HFZ-420
1390 Piccard Drive
Rockville, Maryland 20850

Re: K896422 Burron Ambulatory Drug Delivery System
Additional Information

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   All materials used in this device meet or exceed the USP Class VI requirements.

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I trust this satisfies your requirements. If there are any questions about this information, please contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator
005-060

cc: W. Barrett
E. Brobst
R. Larson
K. Raines
T. Ronca

RETURN RECEIPT REQUESTED---CERTIFIED MAIL # P 333 734 872

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SERVICE TO THE MEDICAL PROFESSION AROUND THE WORLD

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)
1390 Piccard Drive
Rockville, Maryland 20850

MARCH 20, 1990

BURRON MEDICAL, INC.
ATTN: PEGGY KEIFFER
824 TWELFTH AVENUE
BETHLEHEM, PA 18018

D.C. Number : K896422
Received : 03-20-90
90th Day : 06-18-90
Product : BURRON AMBULATORY DRUG DELIVERY SYSTEM

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. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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K896422/B

BURRON MEDICAL INC.

B. Braun of America Company • 824 Twelfth Avenue • Bethlehem, PA 18018

Telephone: (215) 691-5400
Telex: 6855207 BURRON BETM
Telefax: 215-691-2202

March 6, 1990

MAR 2 0 1990

Ms Amalie Matten
FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: K896422 Burron Ambulatory Drug Delivery System
Additional Information

Dear Ms Matten:

Enclosed is the additional information requested by phone on February 22, 1990 for the 510k submission # K896422, Burron Ambulatory Drug Delivery System.

1. Provide the sterilization method and a description of sterilization cycle validation.

The Burron Ambulatory Drug Delivery System is sterilized (b)(4) (b)(4) (b)(4) (b)(4) is enclosed. See Exhibit 1.

2. A general description of the packaging.

The Burron Ambulatory Drug Delivery System is packaged in a tyvek pouch with a product insert card and instructions for use. The pouch is 6.06 in. x 14.63 in. The pouch top web is 48 GA polyester 2 ml LDPE. The bottom web is 1073B grade DuPont Tyvek.

3. Provide the method for determination of non-pyrogenic.

The Clinical Laboratory standard test procedure for determination of pyrogenicity is the Limulus Amebocyte Lysate (LAL) Method. A description of the LAL method procedure is enclosed. See Exhibit 2.

4. Provide the sterility assurance level.

The sterility assurance level (SAL) = 10^{-4}.

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5. Provide the maximum (b)(4) (b)(4) left on the device.

(b)(4)

(b)(4)

I trust this satisfies your requirements. If there are any questions about this information, please contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator
003-025

cc: W. Barrett
E. Brobst
R. Larson
T. Ronca

RETURN RECEIPT REQUESTED--CERTIFIED MAIL #P 333 734 703

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Exhibit 1

STERILIZER (b)(4) (b)(4) SUMMARY

(b)(4)

(b)(4)

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STERILIZER (b)(4) SUMMARY

(b)(4)

(b)(4)

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STERILIZER (b)(4) SUMMARY

(b)(4)

(b)(4)

(b)(4)

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BURRON MEDICAL INC.

CLINICAL LABORATORY STANDARD TEST PROCEDURE

SECTION V:

STP TITLE:

APPLICATION:

FACILITY:

STP NO:

DATE WRITTEN:

WRITTEN & COMPILED BY:

REVISED BY:

REVISION DATE:

REVIEW DATE:

(b)(4)

(b)(4)

1.0.0. STP 800 - SECTION TITLES

(b)(4)

(b)(4)

2.0.0. EQUIPMENT AND MATERIALS REQUIRED:

(b)(4)

(b)(4)

13

2.0.0. EQUIPMENT AND MATERIALS REQUIRED (Cont'd):

(b)(4)

(b)(4)

3.0.0. DEFINITIONS CONDITIONS:

(b)(4)

(b)(4)

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3.0.0. DEFINITIONS CONDITIONS (Cont'd):

(b)(4)

(b)(4)

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3.0.0. DEFINITIONS CONDITIONS (Cont'd):

(b)(4)

(b)(4)

4.0.0. PREPARATION OF GLASSWARE:

(b)(4)

(b)(4)

5.0.0. REAGENT PREPARATION:

(b)(4)

(b)(4)

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5.0.0. REAGENT PREPARATION (Cont'd):

(b)(4)

(b)(4)

6.0.0. SPECIMEN COLLECTION AND PREPARATION:

(b)(4)

(b)(4)

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7.0.0. INHIBITION OR ENHANCEMENT TEST:

(b)(4)

(b)(4)

8.0.0. TEST PROTOCOL, PROPER:

(b)(4)

(b)(4)

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8.0.0. TEST PROTOCOL, PROPER (Cont'd):

(b)(4)

(b)(4)

9.0.0. INTERPRETATION OF RESULTS:

(b)(4)

(b)(4)

10.0.0. STORAGE OF MATERIALS:

(b)(4)

(b)(4)

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10.0.0. STORAGE OF MATERIALS (Cont'd):

(b)(4)

(b)(4)

11.0.0. REFERENCES AND APPENDICES:

(b)(4)

(b)(4)

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TABLE I

Establishment of Product Compatibility, and LAL Problem Solving

INTERPRETATION OF RESULTS OF INHIBITION TESTING

	RESULTS		
(b)(4)			

(b)(4)

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BURRON MEDICAL INC.

APPENDIX ii

BREAKDOWN OF TABLE I PRODUCT GROUPINGS

1. Group A - (b)(4)

2. Group B -

3. Group C -

4. Group D -

(b)(4)

5. Group E -

6. Group F -

7. Group G -

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TABLE I: SOLUTION PREPARATION FOR PYROGEN TESTING BY PRODUCT GROUP

Product Group (See Appendix ii)	Units/ Lot	Effluent Vol. per Lot	Test Solution Preparation Methodology
(b)(4)			

(b)(4)

(continued)

TABLE I: SOLUTION PREPARATION FOR PYROGEN TESTING BY PRODUCT GROUP (continued)

Product Group (See Appendix ii)	Units/ Lot	Effluent Vol. per Lot	Test Solution Preparation Methodology
(b)(4)			

(b)(4)

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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)
1390 Piccard Drive
Rockville, Maryland 20850

FEBRUARY 23, 1990

BURRON MEDICAL, INC.
ATTN: PEGGY KEIFFER
824 TWELFTH AVENUE
BETHLEHEM, PA 18018

D.C. Number: K896422
Product : BURRON AMBULATORY DRUG DELIVERY SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

When your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-89-6422

2/23/90

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
BURRON MEDICAL, INC. ATTN: PEGGY KEIFFER 824 TWELFTH AVENUE BETHLEHEM, PA 18018	10/31/89	11/08/89	04/17/90
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K896422
SHORT NAME: BURRMEDI	ESTABLISHMENT NO: 2521402		

TO:	CONT. CONF.: ?
ODE/DMC	STATUS : H
	REV PANEL : HO
	PAN/PROD CODE(S): HO/ / /

SUBJECT:
BURRON AMBULATORY DRUG DELIVERY SYSTEM

DECISION:	RQST INFO DATE: 12/21/89	INFO DUE DATE: 01/20/90
DECISION DATE: / /	DATE: 02/23/90	DATE: 03/25/90
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /
	DATE: / /	DATE: / /

SUPPLEMENT: 01 LTR DATE: 900110 LOGIN DATE: 900117

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date 2/22/90

From REVIEWER(S) - NAME(S) Mattson

Subject 510(k) NOTIFICATION K896422 / A

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data.

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

Additional Comments:

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: _____ 2/23/90
(BRANCH CHIEF) (DATE)

FINAL REVIEW: _____
(DIVISION DIRECTOR) (DATE)

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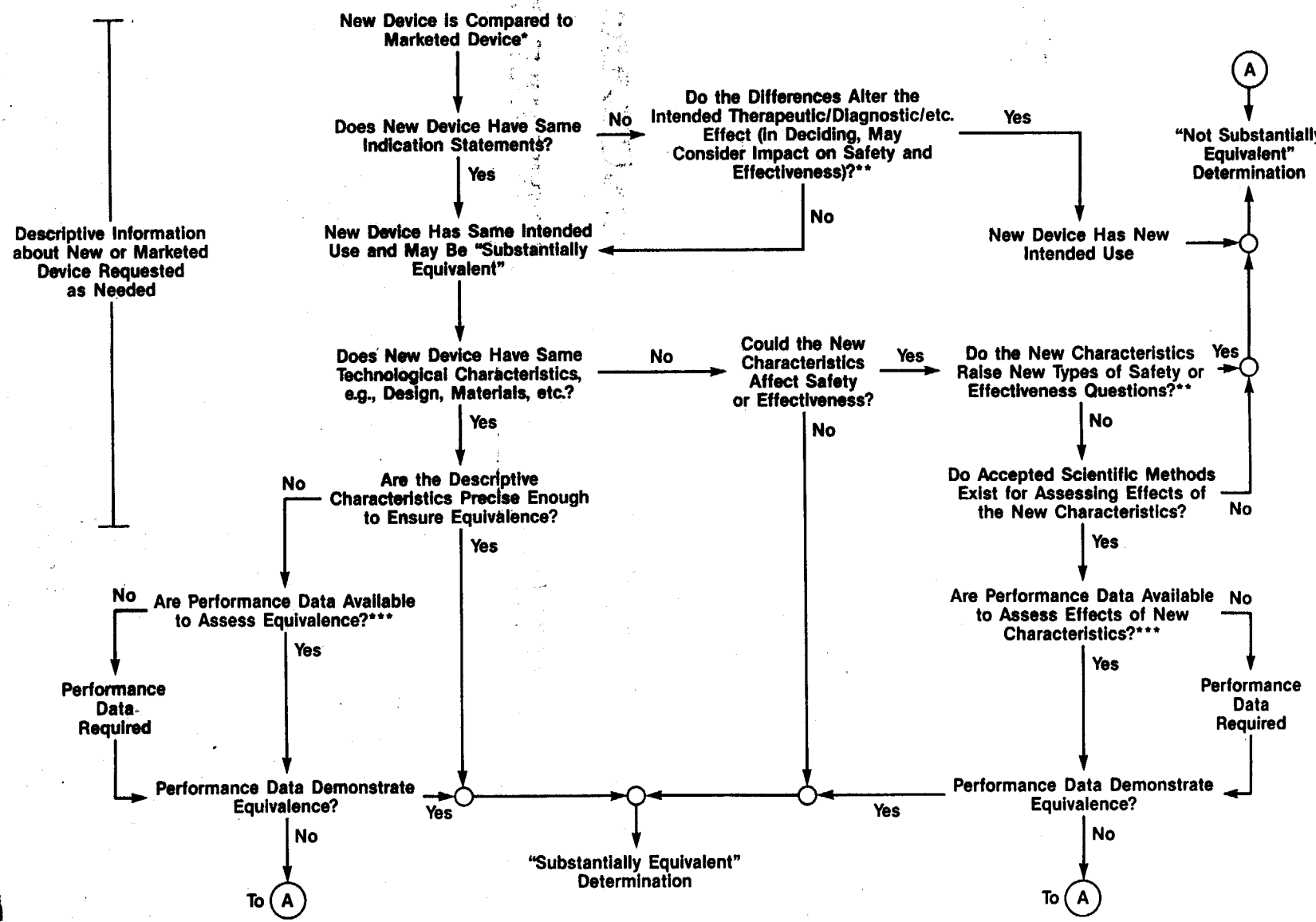
510(k) "Sub ntial Equivalence" Decision-Making Process (Detailed)



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** 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.

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MEMO TO THE RECORD

DATE: 02/22/90 9:55AM

FROM: Biomedical Engineer

DIVISION: DGGD/GH

SUBJECT: Burron Medical Inc.
BURRON AMBULATORY DRUG DELIVERY SYSTEM

I spoke with Peggy Keiffer, Regulatory Affairs Coordinator, and requested sterility information for this device as described in the "510(k) Sterility Review Guidance" Memo.

Ms. Keiffer understands that the 510(k) will be on hold until this additional information is received in the DMC.

Amalie C. Mattan

Amalie C. Mattan

K896422

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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)
1390 Piccard Drive
Rockville, Maryland 20850

JANUARY 17, 1990

BURRON MEDICAL, INC.
ATTN: PEGGY KEIFFER
824 TWELFTH AVENUE
BETHLEHEM, PA 18018

D.C. Number : K896422
Received : 01-17-90
90th Day : 04-17-90
Product : BURRON AMBULATORY DRUG DELIVERY SYSTEM

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. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

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If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

BEST AVAILABLE COPY

K896422/A

BURRON MEDICAL INC.

B. Braun of America Company • 824 Twelfth Avenue • Bethlehem, PA 18018

Telephone: (215) 691-5400
Telex: 6855207 BURRON BETM
Telefax: 215-691-2202

January 10, 1990

FDA-CDRH-ODE

JAN 17 1990

DOCUMENT MAIL CENTER

Ms Amalie Matten
FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

Re: K896422 Burron Ambulatory Drug Delivery System
Additional Information

Dear Ms Matten:

Enclosed is the additional information requested on December 21, 1989 for the 510k submission # K896422, Burron Ambulatory Drug Delivery System.

Question 1. Describe how the rate is set.

The rates are preset using glass capillary tubes of a precision internal orifice to control the flow at either 100ML, 200ML, or 2ML/hr.

Question 2. List all of the materials including the filter material.

a.	Vented Snap Cap	(b)(4) Polyethylene
b.	Backcheck Valve Assembly	Polycarbonate
	Valve Diaphragm	Silicone Rubber
c.	Barrel and Top	Polypropylene
d.	Plunger Tip	Natural Rubber
e.	Plunger Rod	Impact Styrene
f.	Spring	(b)(4) Stainless steel
g.	Extension Tubing	Polyurethane or Polyvinyl Chloride
h.	Air Inlet Filter Assembly Housing	Polyethylene
	Air Inlet Filter	Paper Glass Matrix
i.	Cone Filter Assembly	ABS
j.	Cone Filter	Acrylic Copolymer on Nylon non-woven fabric
k.	Flow Control Adapter Assembly	ABS Housing with Glass Capillary Tube
l.	Halkey-Roberts Clamp	Polycarbonate

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Question 3. Explain the purpose of the filter.

The In-line Filter is for filtration of particulate matter 5 micron and larger.

Question 4. Provide a device sample, engineering drawing, or a photograph of the device.

Enclosed is an engineering drawing of the device. See Exhibit A.

Question 5. Provide information about the accuracy of delivery for each size system.

The accuracy of delivery for each size device is the stated flow rate $\pm$ 15%.

Question 6. Compare the Burron system to the ADFuse system.

Enclosed is a comparison chart showing the similarities and differences between the Burron system and the ADFuse system. See Exhibit B.

I trust this satisfies your requirements. If there are any questions about this information, please contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator
001-003

cc: W. Barrett
E. Brobst
R. Larson
T. Ronca

RETURN RECEIPT REQUESTED--CERTIFIED MAIL

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EXHIBIT A

(b)(4)

(b)(4)

(b)(4), (b)

(b)(4), (b)(5)

33

JAN 06 [illegible]

SHT. 1 OF 1

TOLERANCES UNLESS NOTED: DECIMALS: FRACTIONS: ANGLES:

BURRON MEDICAL INC.
Bethlehem, PA 18015
B. Braun of America Company

AMBULATORY DRUG DELIVERY DEVICE ASSEMBLY

PART OR PRODUCT NO.:

APPROVED BY: [illegible] 1-5-90

DATE 1-4-90 MT

SCALE 2:1

DWG. NO. PRE-446

REV. NO.

NO.	REVISIONS	DATE	APPD.

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DRAWING THIS DRAWING IS THE PROPERTY OF BURRON MEDICAL INC. INFORMATION HEREON IS CONFIDENTIAL – UNAUTHORIZED USE IS PROH

	BURRON AMBULATORY DRUG DELIVERY SYSTEM	HEALTHTEK ADFUSE
Method of Operation	Spring Powered	Spring Powered
Capacity	100mL	60mL
Flow Rate	100mL/hr, 200mL/hr, 2mL/hr.	75mL/hr, 120mL/hr, 40mL/hr
In-Line Filter	2mL/hr, 100mL/hr, 200mL/hr Available with 5micron in-line filter	All sizes Available only with 5.0micron filter
Administration Set	Attached to device	Separate unit, attached after device is filled
Filling Port	Utilizes a one-way valved port to fill device, utilizes a different fluid path to deliver medication through administration set	Utilizes the same port to fill device deliver medication through administration set

BEST AVAILABLE COPY

BURRON MEDICAL INC.

B. Braun of America Company • 824 Twelfth Avenue • Bethlehem, PA 18018

Telephone: (215) 691-5400
Telex: 6855207 BURRON BETM
Telefax: 215-691-2202

January 10, 1990

Ms Amalie Matten
FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, Maryland 20850

FDA-CDRH-ODE

JAN 17 1990

DOCUMENT MAIL CENTER

Re: K896422 Burron Ambulatory Drug Delivery System
Additional Information

Dear Ms Matten:

Enclosed is the additional information requested on December 21, 1989 for the 510k submission # K896422, Burron Ambulatory Drug Delivery System.

Question 1. Describe how the rate is set.

The rates are preset using glass capillary tubes of a precision internal orifice to control the flow at either 100ML, 200ML, or 2ML/hr.

Question 2. List all of the materials including the filter material.

a.	Vented Snap Cap	(b)(4) Polyethylene
b.	Backcheck Valve Assembly	Polycarbonate
	Valve Diaphragm	Silicone Rubber
c.	Barrel and Top	Polypropylene
d.	Plunger Tip	Natural Rubber
e.	Plunger Rod	Impact Styrene
f.	Spring	(b)(4) Stainless steel
g.	Extension Tubing	Polyurethane or Polyvinyl Chloride
h.	Air Inlet Filter Assembly Housing	Polyethylene
	Air Inlet Filter	Paper Glass Matrix
i.	Cone Filter Assembly	ABS
j.	Cone Filter	Acrylic Copolymer on Nylon non-woven fabric
k.	Flow Control Adapter Assembly	ABS Housing with Glass Capillary Tube
l.	Halkey-Roberts Clamp	Polycarbonate

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Question 3. Explain the purpose of the filter.

The In-line Filter is for filtration of particulate matter 5 micron and larger.

Question 4. Provide a device sample, engineering drawing, or a photograph of the device.

Enclosed is an engineering drawing of the device. See Exhibit A.

Question 5. Provide information about the accuracy of delivery for each size system.

The accuracy of delivery for each size device is the stated flow rate ± 15%.

Question 6. Compare the Burron system to the ADFuse system.

Enclosed is a comparison chart showing the similarities and differences between the Burron system and the ADFuse system. See Exhibit B.

I trust this satisfies your requirements. If there are any questions about this information, please contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator
001-003

cc: W. Barrett
E. Brobst
R. Larson
T. Ronca

RETURN RECEIPT REQUESTED--CERTIFIED MAIL

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EXHIBIT A

(b)(4)

— VENTED SNAP CAP
(b)(4) POLYETHYLENE, NAT.

— NORMALLY CLOSED BACKCHECK [-VALVE ASSY.

— BARREL TOP, ADD DEVICE
POLYPROPYLENE, NAT.

— PLUNGER TIP, SILICONIZED
BLACK RUBBER COMPOUND

— PLUNGER, ADD DEVICE
IMPACT STYRENE, NAT.

— BARREL, ADD DEVICE
POLYPROPYLENE, NAT.

— HALKEY-ROBERTS CLAMP

(b)(4)

— EXTENSION TUBING
PELLETHANE (b)(4) CLEAR
(b)(4) (b)(4)

— SPRING, ADD DEVICE
STAINLESS STEEL

— AIR INLET FILTER ASSEMBLY

— CONE FILTER ASSEMBLY

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37

— FLOW CONTROL ADAPTER ASSEMBLY
w/ VENTED MALE L.L. COVER

JAN 05

(b)(4)

(b)(4)

TOLERANCES UNLESS NOTED: DECIMALS: FRACTIONS: ANGLES:

SHT. 1 OF 1

BURRON MEDICAL INC.
Bristol, PA 19015
A Braun of America Company

AMBULATORY DRUG DELIVERY DEVICE ASSEMBLY

PART OR PRODUCT NO.:

APPROVED BY: 1-5-90

DATE 1-4-90 MT

SCALE 2:1

DWG. NO. PRE-446

REV. NO.

NO.	REVISIONS	DATE	APPD.

CAUTION: THIS DRAWING IS THE PROPERTY OF BURRON MEDICAL INC. INFORMATION HEREON IS CONFIDENTIAL - UNAUTHORIZED USE IS PROHIBITED

EXHIBIT B

	BURRON AMBULATORY DRUG DELIVERY SYSTEM	HEALTHTEK ADFUSE
Method of Operation	Spring Powered	Spring Powered
Capacity	100mL	60mL
Flow Rate	100mL/hr, 200mL/hr, 2mL/hr.	75mL/hr, 120mL/hr, 40mL/hr
In-Line Filter	2mL/hr, 100mL/hr, 200mL/hr Available with 5micron in-line filter	All sizes Available only with 5.0micron filter
Administration Set	Attached to device	Separate unit, attached after device is filled
Filling Port	Utilizes a one-way valved port to fill device, utilizes a different fluid path to deliver medication through administration set	Utilizes the same port to fill device deliver medication through administration set

38

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(b)(4)

(b)(4)

VENTED SNAP CAP
(b)(4) POLYETHYLENE, NAT.

NORMALLY CLOSED BACKCHECK T-VALVE ASSY.

BARREL TOP, ADD DEVICE
POLYPROPYLENE, NAT.

PLUNGER TIP, SILICONIZED
BLACK RUBBER COMPOUND

PLUNGER, ADD DEVICE
IMPACT STYRENE, NAT.

BARREL, ADD DEVICE
POLYPROPYLENE, NAT.

HALKEY-ROBERTS CLAMP

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EXTENSION TUBING
PELLETHANE (b)(4) CLEAR

FOI - Page 42 of 60

(b)(4)

(b)(4)

(b)(4)

(b)(4)

EXHIBIT A

SPRING, ADD DEVICE
STAINLESS STEEL

AIR INLET FILTER ASSEMBLY

CONE FILTER ASSEMBLY

FLOW CONTROL ADAPTER ASSEMBLY
w/ VENTED MALE L.L. COVER

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PRINTED
JAN 05 [illegible]

42

SHT 1 OF 1

TOLERANCES UNLESS NOTED: DECIMALS: FRACTIONS: ANGLES:

BURLOW MEDICAL INC.

AMBULATORY DRUG DELIVERY
DEVICE ASSEMBLY

PART OR ASSEMBLY NO.

APPROVED BY

DWG

NO. REVISIONS DATE APPD

(b)(4)

(b)(4)

VENTED SNAP CAP
(b)(4) POLYETHYLENE, NAT.

NORMALLY CLOSED BACKCHECK T-VALVE ASSY.

BARREL TOP, ADD DEVICE
POLYPROPYLENE, NAT.

PLUNGER TIP, SILICONIZED
BLACK RUBBER COMPOUND

PLUNGER, ADD DEVICE
IMPACT STYRENE, NAT.

BARREL, ADD DEVICE
POLYPROPYLENE, NAT.

HALKEY-ROBERTS CLAMP

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EXTENSION TUBING
(b)(4) CLEAR

(b)(4)

(b)(4)

Case 4:16-cv-00169

(b)(4)

(b)(4)

EXHIBIT A

SPRING, ADD DEVICE
STAINLESS STEEL

AIR INLET FILTER ASSEMBLY

CONE FILTER ASSEMBLY

FLOW CONTROL ADAPTER ASSEMBLY
w/ VENTED MALE L.L. COVER

PRINTED
JAN 05 1990

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46

SHT. 1 OF 1

TOLERANCES UNLESS NOTED: DECIMALS: FRACTIONS: ANGLES:

NO.	REVISIONS	DATE	APPD.

BURRON MEDICAL INC.
Bethlehem, PA 18018
B. Braun of America Company

AMBULATORY DRUG DELIVERY DEVICE ASSEMBLY

PART OR PRODUCT NO.:

APPROVED BY: 1-5-90

DATE 1-4-90 MT

SCALE 2:1

DWG. NO. PRE-446

REV. NO.

CAUTION THIS DRAWING IS THE PROPERTY OF BURRON MEDICAL INC. INFORMATION HEREON IS CONFIDENTIAL - UNAUTHORIZED USE IS PROHIBITED.

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)
1390 Piccard Drive
Rockville, Maryland 20850

DECEMBER 21, 1989

BURRON MEDICAL, INC.
ATTN: PEGGY KEIFFER
824 TWELFTH AVENUE
BETHLEHEM, PA 18018

D.C. Number: K896422
Product : BURRON AMBULATORY DRUG DELIVERY SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. This information and all correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

When your additional information is received by the Office of Device Evaluation Document Mail Center (address above), the 90-day period will begin again.

If after 30 days the requested information is not received, we will stop reviewing your submission and proceed to withdraw your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and the 90-day time period will begin again.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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DO NOT REMOVE THIS ROUTE SLIP!!!!

K-89-6422 12/21/89

FROM:	LETTER DATE	LOGIN DATE	DUE DATE
BURRON MEDICAL, INC. ATTN: PEGGY KEIFFER 824 TWELFTH AVENUE BETHLEHEM, PA 18018	10/31/89	11/08/89	02/06/90
	TYPE OF DOCUMENT: 510 (k)		CONTROL # K896422
SHORT NAME: BURRMEDI	ESTABLISHMENT NO: 2521402		

ODE/DMC	CONT. CONF.: ? STATUS : H REV PANEL : HO PAN/PROD CODE(S): HO/ / /	

SUBJECT:
BURRON AMBULATORY DRUG DELIVERY SYSTEM

DECISION: DECISION DATE: / /	RQST INFO DATE: 12/21/89 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /	INFO DUE DATE: 01/20/90 DATE: / / DATE: / / DATE: / / DATE: / / DATE: / /

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date 12/21/89

From REVIEWER(S) - NAME(S) Mattan

Subject 510(k) NOTIFICATION K896422

To THE RECORD

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

_____ (A) Is substantially equivalent to marketed devices.

_____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

✓ (C) Requires more data.

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

Additional Comments:

The submitter requests under 21 CFR §807.95:

_____ No Confidentiality

✓ Confidentiality for 90 days

_____ Continued Confidentiality exceeding 90 days

Predicate Product Code w/Panel and class:

_____

Additional Product Code(s) w/Panel (optional):

_____

REVIEW: DM 12/21
(BRANCH CHIEF) (DATE)

FINAL REVIEW: _____
(DIVISION DIRECTOR) (DATE)

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X
49

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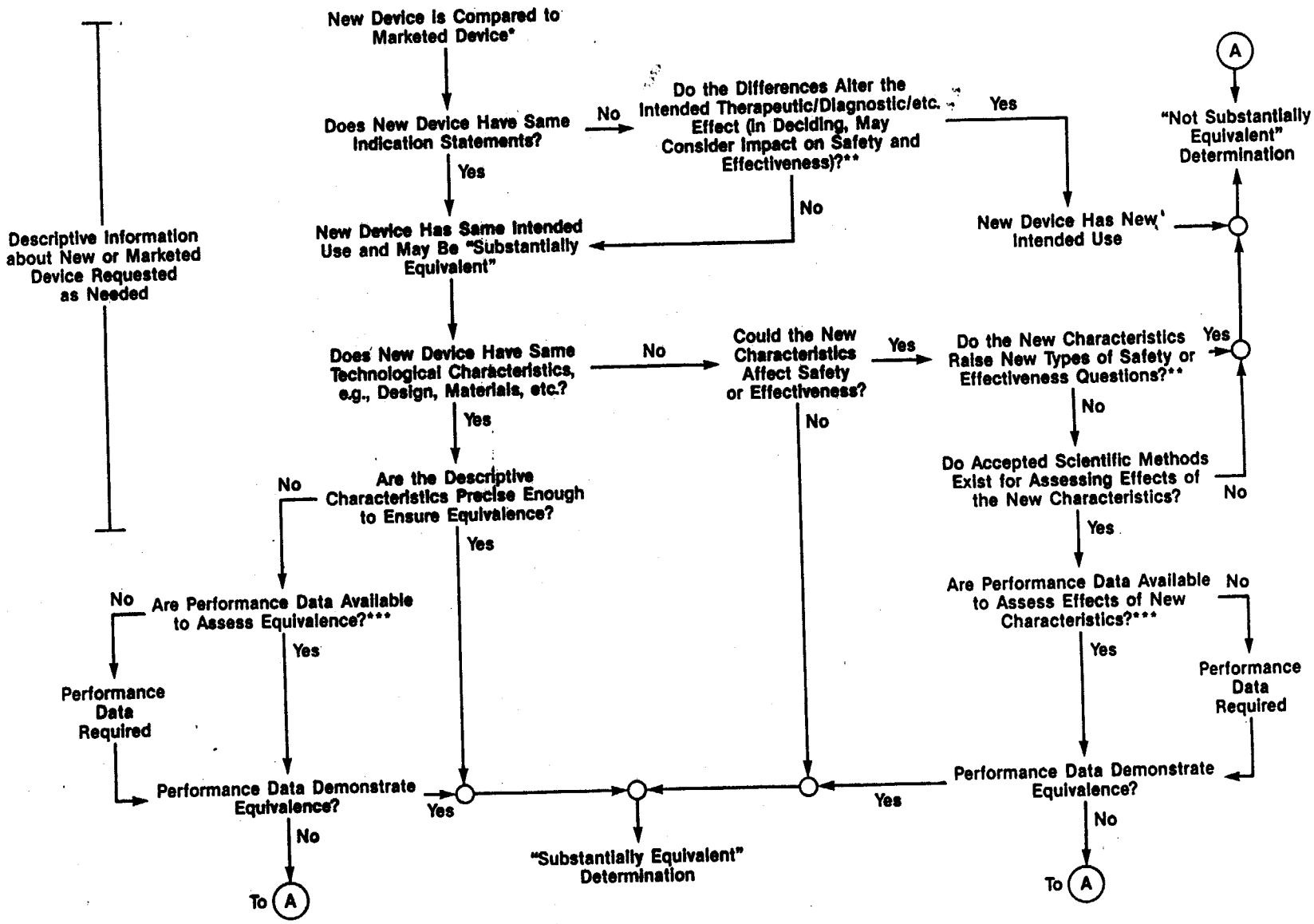
510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 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.

MEMO TO THE RECORD **DATE:** 12/21/89 8:05AM

FROM: Biomedical Engineer **DIVISION:** DGGD/GH

SUBJECT: Burron Medical, Inc.
BURRON AMBULATORY DRUG DELIVERY SYSTEM

I spoke with Peggy Keiffer,Regulatory Affairs Coordinator and requested the following additional information:

1. a description of how the infusion rate is set,
2. a list of materials composing the device (including the filter),
3. the purpose of the filter,
4. the accuracy of each size, and
5. a comparison with a claimed substantially equivalent device.

Ms. Keiffer understands that the 510(k) will be on hold until this additional information is received in the DMC.

Amalie C. Mattan

Amalie C. Mattan

K896422

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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)
1390 Piccard Drive
Rockville, Maryland 20850

NOVEMBER 9, 1989

BURRON MEDICAL, INC.
ATTN: PEGGY KEIFFER
824 TWELFTH AVENUE
BETHLEHEM, PA 18018

D.C. Number : K896422
Received : 11-08-89
90th Day : 02-06-90
Product : BURRON AMBULATORY DRUG DELIVERY SYSTEM

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug, and Cosmetic Act for the above referenced device has been received and assigned an unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. We intend to complete our review expeditiously and within ninety days. Occasionally, however, a submitter will not receive a final decision or a request for additional information until after ninety days has elapsed. Be aware that FDA is able to continue the review of a submission beyond the ninety day period and might conclude that the device is not substantially equivalent. A "not substantially equivalent" device may not be in commercial distribution without an approved premarket approval application or reclassification of the device. We, therefore, recommend that you not market this device before FDA has made a final decision. Thus, if you have not received a decision within ninety days, it would be prudent to check with FDA to determine the status of your submission.

All correspondence concerning your submission MUST be sent to the Document Mail Center at the above address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification application. Telefax material will not be accepted nor considered as part of your official premarket notification application, unless specifically requested of you by an FDA official.

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at (301) 443-6597 or their toll-free number (800) 638-2041, or contact me at (301) 427-1190.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

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K896422

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1989 NOV -8 PM 1:34

CENTER

BURRON MEDICAL INC.

B. Braun of America Company

824 Twelfth Avenue
Bethlehem, PA 18018
Telephone: 215-691-5400
TWX: 510 651 2153 BURRON BETM

October 31, 1989

FOOD AND DRUG ADMINISTRATION
Office of Device Evaluation
510k Document Mail Center (HFZ-401)
1390 Piccard Drive
Rockville, MD 20850

Establishment Registration
2521402

RE: 510(k) Premarket Notification for Burron Ambulatory Drug Delivery System

Dear Sir/Madam:

In accordance with Section 510(k), of the Federal Food, Drug, and Cosmetic Act, Burron Medical Inc., intends to introduce into interstate commerce Burron Ambulatory Drug Delivery System.

Attached please find the 510(k) Premarket Notification for Burron Ambulatory Drug delivery System.

Your prompt attention to this submission will be greatly appreciated. If you have any questions concerning the content of this submission, please do not hesitate to contact me.

Very truly yours,

BURRON MEDICAL INC.

Peggy Keiffer
Regulatory Affairs Coordinator

cc: W. Barrett
E. Brobst
R. Larson
T. Ronca

RETURN RECEIPT REQUESTED--CERTIFIED MAIL #P 333 734 833

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SERVICE TO THE MEDICAL PROFESSION AROUND THE WORLD

05B

510(k) PREMARKET NOTIFICATION

BURRON AMBULATORY DRUG DELIVERY SYSTEM

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BURRON MEDICAL INC.

(A)	PRODUCT NAME:	Ambulatory Drug Delivery System
	TRADE NAME:	Burron Ambulatory Drug Delivery System
	CLASSIFICATION NAME:	Pump, Infusion
(B)	ESTABLISHMENT:	Burron Medical Inc. is the manufacturer. Establishment registration number is # 2521402
(C)	CLASSIFICATION:	Pump, Infusion is classified as a Level II device and assigned code number 80 FRN
(D)	ACTION TAKEN:	Action under section 514 has not been taken since it is believed that specific performance standards have not been promulgated for Infusion Pumps.
(E)	SUBSTANTIAL EQUIVALENCY:	The Burron Ambulatory Drug Delivery System is substantially equivalent in materials, composition, and indication to the ADFuse Ambulatory IV Infusion System, which is currently in commercial distribution, and is manufactured by Healthtek.
(F)	LABELING AND DIRECTIONS FOR USE:	Attached is a draft copy of the labeling and Directions for Use for the Burron Ambulatory Drug Delivery System.
(G)	COMPARATIVE LABELING:	Attached is a copy of the labeling and direction for use of the ADFuse Ambulatory IV Infusion System.
(H)	CATALOG DESCRIPTION:	Attached is a copy of the catalog description of Burron Ambulatory Drug Delivery System.

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(I) CONFIDENTIALITY:

We request that the information in this submission be considered confidential due to its marketing significance.

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LABELING

DIRECTIONS FOR USE

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BURRON AMBULATORY DRUG DELIVERY SYSTEM

For continuous infusion of solutions

Contents of unopened, undamaged package are:
STERILE * NONPYROGENIC

PRODUCT CODE
XXX-XXX

CONTENTS:
ONE - Drug Delivery System with attached fixed rate administration set
ONE - Transport Bag
ONE - Patient Label

Approximate Priming Volume = _____mL.

Disposable - Destroy after single use.

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

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BURRON MEDICAL INC.
824 Twelfth Avenue
Bethlehem PA 18018
B. Braun of America Company

B.BRAUN

DIRECTIONS FOR FILLING

Use Aseptic Technique. Prepare solutions as prescribed by manufacturer.

1. Remove protective cover from female luer lock filling port.
2. Tighten protective cap on administration set and close on/off clamp.
3. Attach Multi-AD Syringe System or other device to filling port.
4. Fill with desired volume of solution. Confirm volume with graduations on the side of device.
5. Replace the protective cover onto filling port.
6. Prime set by removing the protective cap and opening on/off clamp. Solution will automatically flow into administration set. The set requires only seconds to prime.
7. Visually check for fluid flow through administration set and removal of all entrapped air.
8. Close on/off clamp and securely attach protective cap provided separately in package.
9. Apply patient label to reservior.
10. Package filled system in Transport Bag for delivery to patient.
11. Refer to drug manufacturer's package insert for storage requirements.

DIRECTIONS FOR USE

1. Assure solution is at room temperature before starting infusion.
2. Assure correct patient name, medication content, fluid volume and integrity of the System.
3. Use aseptic technique. Close on/off clamp. Remove protective cap on distal end of administration set. Verify that set has been primed. Securely attach set to patient using distal luer lock connector.
4. Open on/off clamp to begin infusion. Record start time on label.
5. When system is empty, secure luer cap and discard unit in accordance with local environmental policy.

Note: Monitor infusion rate by observing movement of plunger over a period of time.
Note: Removal of protective end cap will initiate fluid flow if on/off clamp is open.
Note: System must be worn by patient during infusion.
AXXXXXXXXXXX 9/89

DRAFT

AMBULATORY DRUG DELIVERY SYSTEM

DESCRIPTION

The BURRON Drug Delivery System is a complete, lightweight disposable device which uses a constant internal pressure to infuse medication at a fixed rate. When filled, the device operates with internal energy provided by a precision compression spring. The contents are delivered through a filter (when provided) and a controlled size orifice.

The System is designed to deliver a maximum of 100mL of medication. It provides a continuous medication flow over infusion period, either 100mL/hr, 200mL/hr or 2mL/hr +/-15%.

INDICATIONS AND USAGE

The System is indicated for patients requiring slow, continuous intravenous administration of medications. It is convenient for use by ambulatory patients.

It is user's responsibility to assure that medication is prepared and administered according to drug manufacturer's package insert.

CONTRAINDICATIONS

Not designed for infusion of blood, plasma products and large volumes of fluid.

WARNINGS

Do not fill past _____cc if device and contents are to be frozen. To thaw frozen contents, let stand at room temperature or in refrigerator according to drug manufacturer's recommendations. Do not microwave.

Disposable - destroy unit after single use. The unit must not be refilled or resterilized.

System must be filled according to procedures described under DIRECTIONS FOR FILLING. Do not fill device with more than 105 mL of medication.

Do not use while swimming, or during excessive physical activity.

System must be worn by patient during infusion.

DIRECTIONS FOR FILLING

Use Aseptic Technique. Prepare solutions as prescribed by manufacturer.

1. Remove protective cover from female luer lock filling port.

2. Tighten protective cap on administration set and close on/off clamp.

3. Attach appropriate Multi-AD Syringe System or other device to filling port.

4. Fill with desired solution volume. Confirm volume with graduations on side of reservior.

5. Replace protective cover onto filling port.

6. Prime set by removing protective cap and opening on/off clamp. The solution will automatically flow into the administration set. The set requires only seconds to prime.

7. Visually check for fluid flow through administration set and removal of all entrapped air.

8. Close on/off clamp and securely attach protective cap provided separately in package.

9. Affix patient label to reservior.

10. Package filled System in Transport bag for delivery to patient.

11. Refer to drug manufacturer's package insert for storage requirements.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

BURRON MEDICAL INC.
824 Twelfth Avenue
Bethlehem PA 18018
B. Braun of America Company

B.BRAUN

BEST AVAILABLE COPY

DIRECTIONS FOR ADMINISTRATION

1. Assure solution is at room temperature before starting infusion.

2. Assure correct patient name, medication content, fluid volume and integrity of the System.

3. Use aseptic technique. Close on/off clamp. Remove protective cap on distal end of the administration set. Verify that administration set has been primed. Securely attach set to patient using distal luer lock connector.

4. Open on/off clamp to initiate infusion. Record start time on label.

5. When system is empty, replace luer cap and discard unit in accordance with local environmental policy. Disposable - destroy after single use.

Note: Assure system is operating by observing plunger movement over time.

Note: Removal of distal protective cap will initiate fluid flow if on/off clamp is open.

Note: Device must be worn by patient during infusion.

PACKAGE CONTENTS

BURRON Drug Delivery System is supplied in a package that contains the following:

1. Drug Delivery System with attached fixed rate administration set.

2. Transport Bag

3. Patient Labels.

Each case of _____ contains _____ patient carrying accessories.

BURRON MEDICAL INC.
824 TWELFTH AVE.
BETHLEHEM, PA. 18018
B. BRAUN OF AMERICA COMPANY

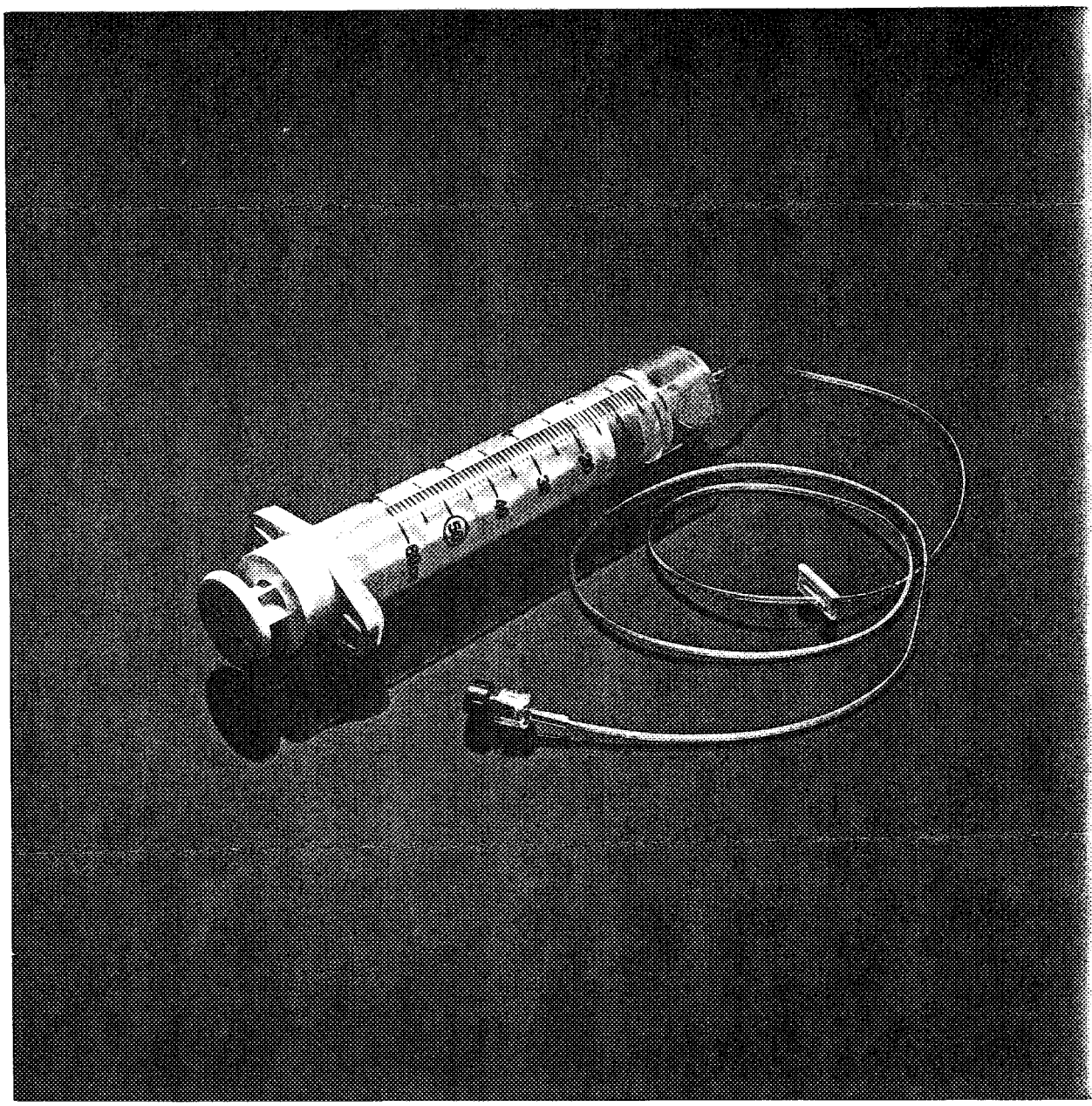
BEST AVAILABLE COPY

COMPARATIVE LABELING:

BEST AVAILABLE COPY

ADFuse™

Ambulatory IV Infusion System



HEALTHTEK

Nevada City
California 95959
(916) 265-9068

BEST AVAILABLE COPY

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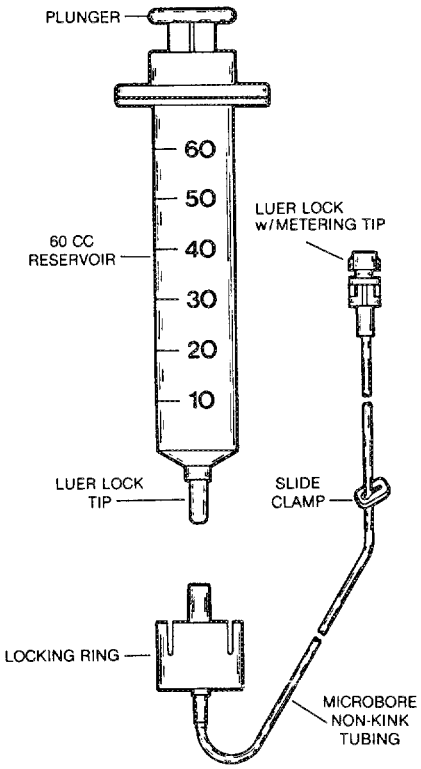
ADFuse™

Ambulatory IV Infusion System

A COST EFFECTIVE SMALL VOLUME IV INFUSION DEVICE DESIGNED TO SIMPLIFY DRUG DELIVERY FOR AMBULATORY PATIENTS



ADFUSE FEATURES	RELATED BENEFITS
▶ Operates without batteries, motors, or electronic circuits	▶ Eliminates expensive acquisition, maintenance and repair costs
▶ Similar in size and weight to a 60cc syringe	▶ Small size and light weight aid ambulatory patients
▶ Fills like ordinary 60cc syringe	▶ No dangerous "blow back" of medications
	▶ Eliminates additional disposables
▶ Graduated in 1cc increments	▶ Aids in identifying volumes during filling and administration
▶ Preset infusion rate controlled by precision metering tip	▶ Patient cannot change infusion rate
▶ Built in spring gently infuses the IV solution regardless of position	▶ Can be carried in pouch, hung from IV stand, or placed at bed side
▶ Can be refrigerated or frozen after filling	▶ Provides convenient long term storage for many medications
▶ Fluid path is made from materials compatible with most medications	▶ Allows standardization with one delivery system
▶ Tamper resistant IV administration set	▶ IV set locks to ADFuse body reducing potential leaks and removal of medications
▶ Inline 5 micron filter with naturally hydrophilic membrane	▶ Removes particulates
	▶ No surfactant to wash off into fluid path

ORDERING INFORMATION

Catalog No.	Description	Case Pack
7FS001	60cc delivered in approx. 50 min.	25 each

HEALTHTEK

870 Gold Flat Road
Nevada City, CA 95959
(916) 265-9068
Made in USA

DISTRIBUTED BY:

BEST AVAILABLE COPY

Document 1PA016D 3/89

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FOI - Page 66 of 69

ADFuse™

Directions for Administration

Use aseptic technique where appropriate

1. Close the slide clamp on the ADFuse administration set to prevent fluid flow.
2. Remove red protective cover from the male luer lock on the distal end of the administration set.
3. Carefully connect the administration set to the female luer on a catheter or attach to needle.
4. Open the slide clamp on the ADFuse administration set to begin infusion.
5. After the ADFuse has discharged its contents, disconnect and dispose of in a proper manner.

NOTE: Do not use in bath or shower.

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

Ordering Information

CATALOG #	BOXES/CASE	UNITS/BOX
7FS001	4	25

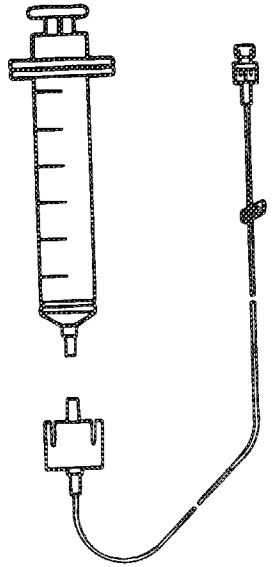
HEALTHTEK

870 GOLD FLAT ROAD
NEVADA CITY, CA 95959
(916) 265-9068
PATENTS PENDING

ADFuse™

Catalog #7FS001

Flow Rate Approximately 1.25 ml/minute
60 ml Capacity – 5.0 Micron Filter
Nonpyrogenic Sterile Fluid Path



- Do not use if visibly damaged.
- Discard after use.
- Do not resterilize or reuse.
- Do not use to administer blood or blood products.
- Fluid path and areas beneath undisturbed protective covers are sterile and nonpyrogenic.
- Do not use in bath, shower, or while swimming.

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

HEALTHTEK

Nevada City
California 95959
(916) 265-9068

1PD076A 12/88

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ADFuse Infusion Rates

ADFuse™

Directions for filling

Use aseptic technique where appropriate

1. Remove protective cover from male luer lock on the ADFuse.
2. Attach needle or other liquid transfer device.
3. Fill ADFuse with the desired volume of liquid. Confirm volume with graduations on the side of the ADFuse.
4. Remove protective cover from female luer lock on the ADFuse administration set.
5. Attach administration set to ADFuse by engaging luer threads and turning clockwise. Do not over-tighten to the point where the threads may be damaged.
6. Before removing the plunger, verify that the red protective cover on the distal end of the administration set is secure.
7. Remove the plunger by unscrewing in a counterclockwise direction. Discard the plunger.
8. Carefully loosen the distal protective cap and allow fluid to prime the administration set.
9. Replace the distal protective cap.
10. Apply a gummed sticker to the ADFuse.
11. Refrigerate if appropriate.

NOTE: Do not use in bath or shower. Do not fill past the 60cc graduation if the ADFuse and contents are to be frozen.

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BURRON MEDICAL INC.

CATALOG DESCRIPTION

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CATALOG DESCRIPTION

Catalog numbers have not yet been assigned.

Burron Ambulatory Drug Delivery System will be sold in various sizes and infusion rates.

2mL/hr
100mL/hr
200mL/hr

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