



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (jsh)
FOLDER: K981318 - 76 pages
COMPANY: BAXTER HEALTHCARE CORP. (BAXTHEAL)
PRODUCT: SET, ADMINISTRATION, INTRAVASCULAR (FPA)
SUMMARY: Product: DUAL LUER LOCK CAP

DATE REQUESTED: Sep 8, 2011

DATE PRINTED: Sep 8, 2011

Note: Printed



K981318

510(k) SUMMARY

Dual Luer Lock Cap

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

April 9, 1998

Proposed Device:

Dual Luer Lock Cap

Predicate Device:

Medex Male/Female Luer Lock Plug
B. Braun Blue Cap Dual Function Lock Lock Plug
Abbott Male/Female Sterile Cap

Proposed Device Description:

The subject of this submission is a sterile Dual Luer Lock Cap which will be used to cover male or female luer ports on medical devices. The proposed Dual Luer Lock Cap will replace the existing port cap on a number of currently marketed Baxter devices such as sets, stopcocks and manifolds. It will also be sold individually as a replacement cap to cover an open luer port after it has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end.

Statement of Intended Use:

The Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

April 9, 1998

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Dual Luer Lock Cap is similar in design characteristics to several other marketed sterile replacement caps which feature a dual male/female luer connection. These include the Medex Male/Female Luer Lock Plug, the B. Braun Blue Cap Dual Function Lock Lock Plug and the Abbott Male/Female Sterile Cap. It is also similar to the existing port cap on Baxter's MultiPort Manifold.

There are no new materials involved in the proposed device. It is comprised of the same material used to fabricate the current port protector on Baxter's marketed MultiPort Manifold.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed Dual Luer Lock Cap have been generated. A description of the functional testing along with test results has been provided. The data indicate that the proposed cap meets or exceed all functional requirements and support its suitability for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1998

Ms. Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

Re: K981318
Trade Name: Dual Luer Lock Cap
Regulatory Class: II
Product Code: FPA
Dated: April 9, 1998
Received: April 10, 1998

Dear Ms. Snyder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

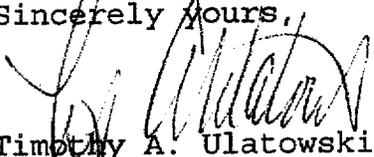
Page 2 - Ms. Snyder

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Premarket Notification
Dual Luer Lock Cap

510(k) Number: Not Available

Device Name: Dual Luer Lock Cap

Indication for Use:

Baxter's Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

Patricia Cuente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981318

Prescription Use _____
(Per 21 CFR 801.109)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 1998

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Baxter Healthcare Corporation
I.V. Systems Division
Route 120 and Wilson Road
Round Lake, Illinois 60073

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Trade Name: Dual Luer Lock Cap
Regulatory Class: II
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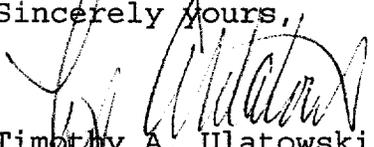
Page 2 - Ms. Snyder

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Sincerely yours,



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

Enclosure

2

510(k) Premarket Notification
Dual Luer Lock Cap

510(k) Number: Not Available

Device Name: Dual Luer Lock Cap

Indication for Use:

Baxter's Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

Patricia Cuente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981318

Prescription Use _____
(Per 21 CFR 801.109)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

4/21/98

Reviewer(s) - Name(s) Brenda Goller

Memorandum

Subject: 510(k) Number 1981318

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review 4/15/98.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate? YES NO

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? 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 indication for use form (required for originals received 1-1-96 and after)

Animal Source Material Human Tissue Product Human Cell Product Human Extraction Product
(Please Check All That Apply)

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

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

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

180 FPA

180

Patricia Cicento
(Branch Chief)

GHDB
(Branch Code)

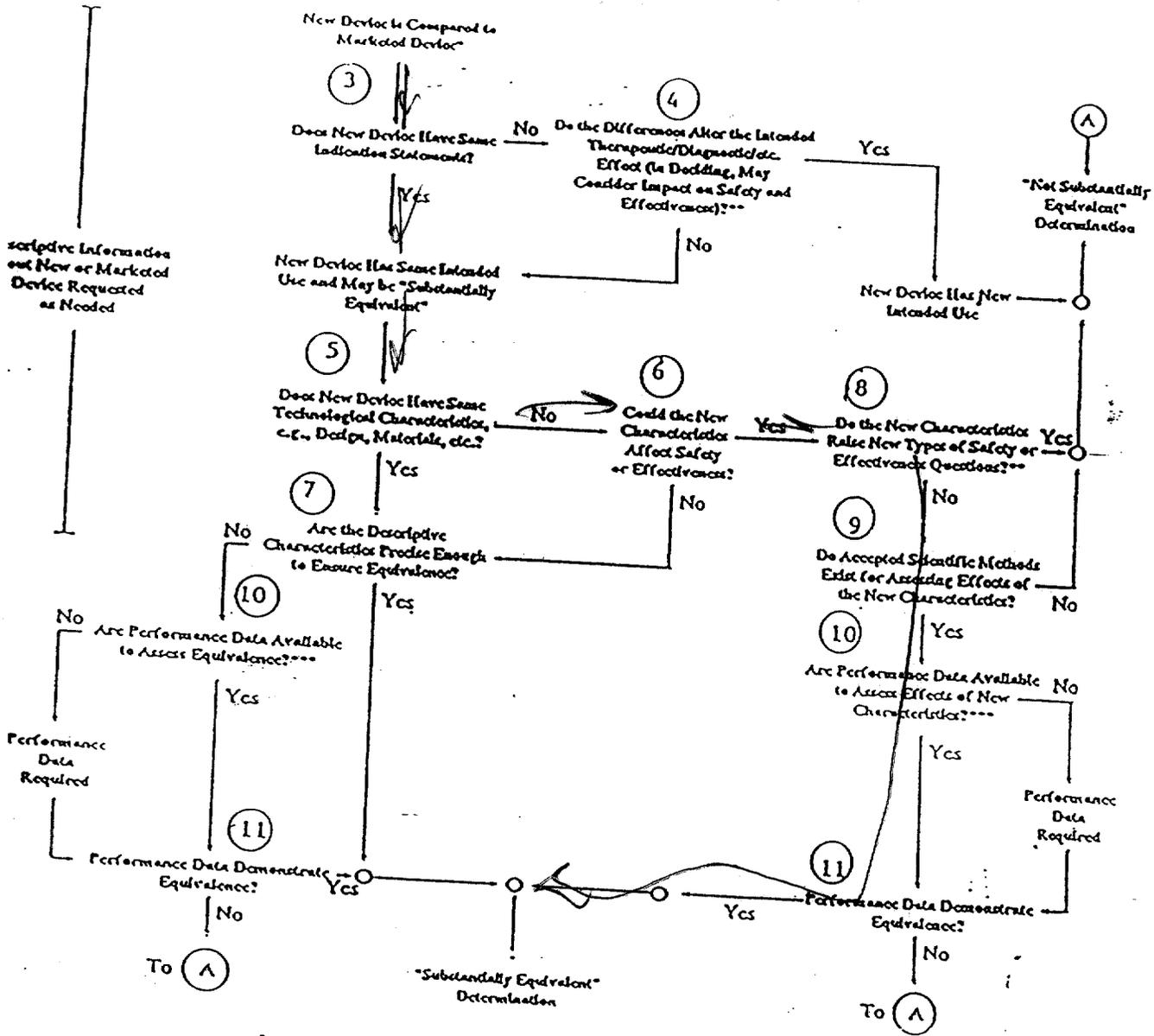
4-22-98
(Date)

Division Review:
(Division Director)

[Signature]
(Date) 4/22/98

d

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.

K981318 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION 4/21/98

Reviewer: Brenda J. Bolden

Division/Branch: DDIGD/GH

Trade Name: Baxter Dual Luer Lock Cap

Common Name: accessory to IV administration set, manifold, stopcock

Panel: 80 **Product Code:** FPA **Class:** II

Product To Which Compared: B. Braun Blue Cap, Medex Male/Female luer lock plug, Abbott male/female sterile cap

510(k) Number: K820454,

	YES	NO	
1. IS PRODUCT A DEVICE?	<u> x </u>	<u> </u>	IF NO STOP
2. DEVICE SUBJECT TO 510(K)?	<u> x </u>	<u> </u>	IF NO STOP
3. SAME INDICATION STATEMENT?	<u> x </u>	<u> </u>	IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	<u> </u>	<u> * </u>	IF YES STOP > NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	<u> </u>	<u> x </u>	IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	<u> x </u>	<u> * </u>	IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	<u> </u>	<u> </u>	IF YES STOP > SE IF NO GO TO 10
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	<u> </u>	<u> * </u>	IF YES STOP > NSE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	<u> x </u>	<u> </u>	IF NO STOP > NSE
10. PERFORMANCE DATA AVAILABLE?	<u> x </u>	<u> </u>	IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	<u> x </u>	<u> * </u>	>

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation below

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: The subject device is used as a cap for male or female luer ports on medical devices such as manifolds, stopcocks, or IV sets. There is no open port for infusing or withdrawing fluids as stated in the labeling.
2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement.

Baxter is claiming equivalency to their MultiPort Manifold (K932512), Medex plug, Abbott cap and B.Braun plug. A comparison chart is included on page 26, section 5 indicating that each device has same intended use, all except the Baxter multiport (female adapters only) are compatible with male or female luer adapters, materials are polyolefin in some and polypropylene (PP) in the Baxter products, with other design feature differences. Baxter believes the Medex device is pre-Amendments (see summary of the Medex antimicrobial luer lock plug under K954970 included in attachment 8, page 35.

The subject device will replace existing port caps on a number of their legally marketed devices (Baxter MultiPort Manifold, K932512; Solution sets with MultiPort, K961225; Stopcock and stopcock manifold gangs, K955782; Extension sets, K811078, K915390, K921899; and 3 port adapter, K913627). It will also be sold as a replacement cap to cover an open port after accessing. The device consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end (see attachment 2 for diagrams, page 20 along with diagrams of it on their manifold). This subject device can be used as a female connector or a male connector; whereas, the current cap is only for one type of connection.

The cap is made of (b)(4) which is the same as their manifold. Baxter includes a biocompatibility certification statement.

The device is sterilized by (b)(4), (b)(4) method, at dose of (b)(4) and packaged in cardboard and blister package.

Draft labeling is included in attachment 6, page 29 followed with predicate labeling. Baxter revised their labeling to delete "this product does not contain latex" to state that it does not contain natural rubber latex since latex free gives a false connotation about not being sensitive to latex.

Functional testing, attachment 5, page 27 includes a summary of tests, standards, sample size, and results to include Luer taper dimensions meets ANSI MD70.1-1983; luer resistance to separation and unscrewing meets same standard; pressure seal resulting in no water leaks at 45 psi; male cap to female luer interface resulting in no leaks, separation, lock up or malfunction; and female cap to male luer inter face with same results as previous test. All samples passed each test.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED
(DELETE QUESTIONS WHICH ARE NOT APPLICABLE)

5. DESCRIBE THE NEW TECHNOLOGICAL CHARACTERISTICS:

The device has a female connector on one end and a male connector on the other end with knurled grip surface; (b)(4) material; integrated male/female design with short post.

6. EXPLAIN HOW THE NEW CHARACTERISTICS COULD/COULD NOT AFFECT SAFETY OR EFFECTIVENESS:

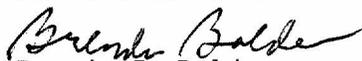
The new characteristics could adversely affect safety or effectiveness if the material was not biocompatible and the luer fittings were not compatible with standard adapters.

8. EXPLAIN THE NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS RAISED OR WHY THE QUESTIONS ARE NOT NEW:

The questions are the same since these types of devices have been previously reviewed in other documents.

11. EXPLAIN HOW THE PERFORMANCE DATA DEMONSTRATE THAT THE DEVICE IS/IS NOT SUBSTANTIALLY EQUIVALENT:

With the inclusion of functional testing of attachments, use of standards, biocompatible material, appropriate labeling, and sterilization information, I believe the device is SE to others of this type.


Brenda J. Bolden
4/21/98

K981318/A1

Baxter

April 16, 1998

Ms. Brenda Bolden
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation, HFZ-480
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED

21 APR 98 08 01

FDA/CDRH/ODE/DMC

**RE: K981318 - Dual Luer Lock Cap
Request for Additional Information**

Dear Ms. Bolden:

We are responding to your phone call of 4/15/98 requesting that the proposed labeling for the device be modified. The statement "This product does not contain latex" has been revised to "This product does not contain natural rubber latex" per your request. Revised draft labeling is attached.

Thank you for your assistance in expediting review of this file. If you have any questions or require additional information, please contact me or Marcia Marconi, Vice President, Regulatory Affairs at (847) 270-4637.

Sincerely,



Mary Ellen Snyder
Regulatory Affairs Manager
(847) 270-4644
(847) 270-4668 (FAX)



Ms. Brenda Bolden
K981318
April 16, 1998

Page 2

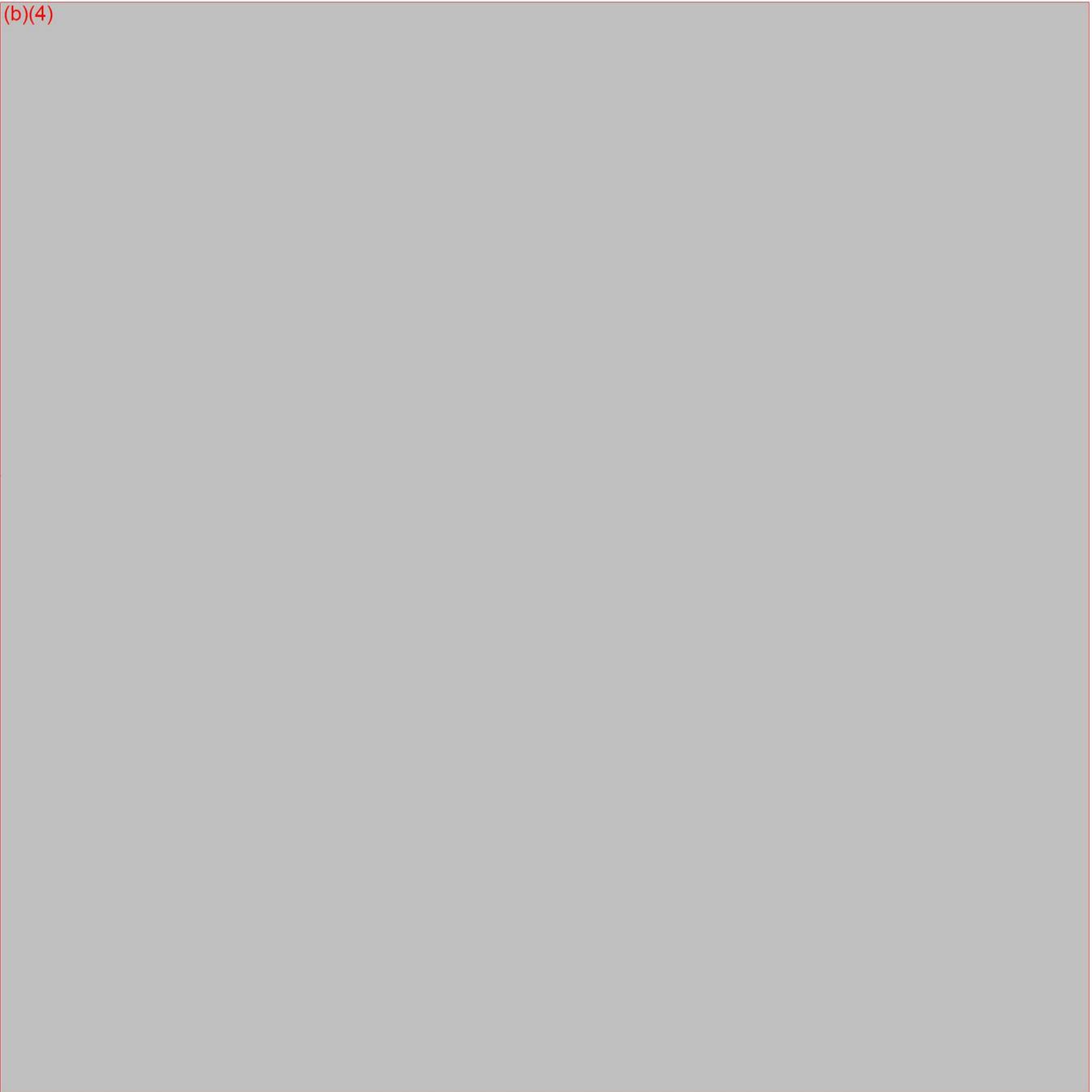
ATTACHMENT 1
REVISED DRAFT LABELING

Ms. Brenda Bolden
K981318
April 16, 1998

Page 3

Attachment 1.0
Revised Draft Labeling - Direction Sheet and Unit Label

(b)(4)



Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Checklist for Premarket Notifications [510(k)s]

Device Trade Name: <i>Dual Luer Lock Cap</i>	K# <i>K981318</i>	
Submitter Name: <i>Baxter Healthcare Corp.</i>		
Date Received: <i>4/14/98</i>		
90 Day Due Date: <i>7/9/98</i>		
Review Tier: 1 <u>(2)</u> 3		
Question	Yes	No
A. Is the product a device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Is the device exempt from 510(k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Expedited Review Status: Requested by sponsor, or identified by PILOT Division Granted by Pilot Division?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
D. Has this device been the subject of a previous NSE decision?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, does this new 510(k) address the NSE Issues(s), e.g., performance data?	<input type="checkbox"/>	<input type="checkbox"/>
E. Has the sponsor been the subject of an integrity investigation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, has the ODE Integrity Officer given permission to proceed with the review?	<input type="checkbox"/>	<input type="checkbox"/>

Decision: ACCEPT ✓ REFUSE TO ACCEPT _____

Administrative Reviewer Signature: *L. Pan* Date: APR 14 1998

Supervisory Signature: *B. Bolde* Date: 4/15/98

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Division of Dental Infection Control, and General Hospital Use Devices (DDIGD)
Screening Checklist for Premarket Notifications [510(k)s]
ELEMENTS ALWAYS REQUIRED MARKED WITH ASTERISK (*)

Device Name: <i>Dual Luer Lock Cap</i> <i>K981318</i>	
Submitter Name: <i>Baxter Healthcare Corp.</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). d) Indication for use statement</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>	
<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>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>	

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Screening Checklist for all Premarket Notification 510(k) Submissions

Device Name: <u>Dual Lined Lock Cap</u>		K 981318					
Submitter (Company): <u>Baxter Healthcare Corp</u>							
Items which should be included <i>(circle missing & needed information)</i>	SPECIAL		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"							
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							
	GO TO #2,4	<input checked="" type="checkbox"/>	GO TO #3,4,5	<input checked="" type="checkbox"/>	GO TO #4,5	<input checked="" type="checkbox"/>	
2. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) STATEMENT - INTENDED USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAS NOT CHANGED*							
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*							
d) Design Control Activities Summary							
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis							
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied							
iii) A declaration of conformity with design controls. The declaration of conformity should include:							
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance were met							
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.							
IF ALL REQUIRED ITEMS ARE NOT PRESENT, GO TO SECTION 4 TRADITIONAL							

→ → → GO TO SECTION 4 ← ← ←

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Screening Checklist for all Premarket Notification 510(k) Submissions

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
	3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS						
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → GO TO SECTION 4 ← ← ←

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Screening Checklist for all Premarket Notification 510(k) Submissions

4. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							✓ IF ITEM IS NEEDED AND IS MISSING
	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number							
b) compliance with Section 513 - device class							
c) OR a statement that the device is not yet classified	may be a classification request; see coordinator						
d) compliance with Section 514 - performance standards							
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) Summary or Statement (FOR ALL DEVICE CLASSES)							
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Verify that Document is labeled Class III for GMP purposes.							
k) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
l) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
iv) MRI compatibility (if claimed)							
m) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing							
vi) safety characteristics							

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

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

Passed Screening Yes No
 Date: 4/15/98

Reviewer: B. Beld
 Concurrence by Review Branch: _____

17

PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

Device Name _____

Division/Branch _____

Administrative Reviewer Signature _____ Date _____

Supervisory Signature _____ Date _____

Did the firm request expedited review? _____ Yes _____ No

Did we grant expedited review? _____ Yes _____ No

Truthful and accurate statement enclosed? _____ Yes _____ No

(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? _____ YES _____ No

(Required for Original 510(k)s received 1/1/96 and after --
must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____ Yes _____ No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial equivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____ Yes _____ No

Accepted

Refuse To
Accept

I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	<input type="checkbox"/>	<input type="checkbox"/>
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	<input type="checkbox"/>	<input type="checkbox"/>
C. Is Device Subject To Review By CDRH?	<input type="checkbox"/>	<input type="checkbox"/>
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision? (ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	<input type="checkbox"/>	<input type="checkbox"/>
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer. (ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	<input type="checkbox"/>	<input type="checkbox"/>
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	<input type="checkbox"/>	<input type="checkbox"/>
1. Device Trade Or Proprietary Name	<input type="checkbox"/>	<input type="checkbox"/>
2. Device Common Or Usual Name Or Classification Name	<input type="checkbox"/>	<input type="checkbox"/>
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	<input type="checkbox"/>	<input type="checkbox"/>
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	<input type="checkbox"/>	<input type="checkbox"/>
5. Classification Panel	<input type="checkbox"/>	<input type="checkbox"/>
6. Action Taken To Comply With Section 514 Of The Act	<input type="checkbox"/>	<input type="checkbox"/>
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	<input type="checkbox"/>	<input type="checkbox"/>

8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	<input type="checkbox"/>	<input type="checkbox"/>
9. For Class III Devices Only, A Class III Certification And A Class III Summary	<input type="checkbox"/>	<input type="checkbox"/>
10. Photographs Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
11. Engineering Drawings For The Device With Dimensions And Tolerances	<input type="checkbox"/>	<input type="checkbox"/>
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	<input type="checkbox"/>	<input type="checkbox"/>
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
14. Data To Show Consequences And Effects Of A Modified Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
15. Truthful And Accurate Statement	<input type="checkbox"/>	<input type="checkbox"/>
II. Additional Information That <u>Is</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Submitter's Name And Address	<input type="checkbox"/>	<input type="checkbox"/>
B. Contact Person, Telephone Number And Fax Number	<input type="checkbox"/>	<input type="checkbox"/>
C. Representative/Consultant If Applicable	<input type="checkbox"/>	<input type="checkbox"/>
D. Table Of Contents With Pagination	<input type="checkbox"/>	<input type="checkbox"/>
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	<input type="checkbox"/>	<input type="checkbox"/>
III. Additional Information That <u>May Be</u> Necessary Under 21 CFR 807.87(h):	<input type="checkbox"/>	<input type="checkbox"/>
A. Comparison Table Of The New Device To The Marketed Device(s)	<input type="checkbox"/>	<input type="checkbox"/>
B. Action Taken To Comply With Voluntary Standards	<input type="checkbox"/>	<input type="checkbox"/>
C. Performance Data	<input type="checkbox"/>	<input type="checkbox"/>
MARKETED DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>
Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
NEW DEVICE:	<input type="checkbox"/>	<input type="checkbox"/>
Bench Testing	<input type="checkbox"/>	<input type="checkbox"/>
Animal Testing	<input type="checkbox"/>	<input type="checkbox"/>

20

Clinical Data	<input type="checkbox"/>	<input type="checkbox"/>
D. Sterilization Information	<input type="checkbox"/>	<input type="checkbox"/>
E. Software Information	<input type="checkbox"/>	<input type="checkbox"/>
Hardware Information	<input type="checkbox"/>	<input type="checkbox"/>
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	<input type="checkbox"/>	<input type="checkbox"/>
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	<input type="checkbox"/>	<input type="checkbox"/>
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	<input type="checkbox"/>	<input type="checkbox"/>
I. Other (Specify)	<input type="checkbox"/>	<input type="checkbox"/>

21

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

"SUBSTANTIAL EQUIVALENCE". (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

*
Division/Branch: _____

Device Name: _____

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

YES NO

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

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

02

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

*

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

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

DB

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

April 13, 1998

BAXTER HEALTHCARE CORP.
RT. 120 & WILSON RD.
ROUND LAKE, IL 60073
ATTN: MARY ELLEN SNYDER

510(k) Number: K981318
Received: 10-APR-1998
Product: DUAL LUER LOCK CAP

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

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

Sincerely yours,

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



510(k) PREMARKET NOTIFICATION

**DUAL LUER LOCK CAP
BAXTER HEALTHCARE CORPORATION**

April 9, 1998

SK-24

HO

Class II

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Premarket Submission Cover Sheet

Date of Submission: **April 9, 1998** FDA Document Number:

Section A **Type of Submission**

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

Section B1 **Reason for Submission ----510(k)s Only**

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

Section B2 **Reason for Submission ----PMAs Only**

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

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 APR 98 13 13
 FDA/CDRH/ODE/DMC

Section B3 **Reason for Submission ----IDEs Only**

<input type="checkbox"/> New Device	<input type="checkbox"/> Change in:	<input type="checkbox"/> Response to FDA letter concerning:
<input type="checkbox"/> Addition of institution	<input type="checkbox"/> Correspondent	<input type="checkbox"/> Conditional approval
<input type="checkbox"/> Expansion/extension of study	<input type="checkbox"/> Design	<input type="checkbox"/> Deemed approved
<input type="checkbox"/> IRB certification	<input type="checkbox"/> Informed consent	<input type="checkbox"/> Deficient final report
<input type="checkbox"/> Request hearing	<input type="checkbox"/> Manufacturer	<input type="checkbox"/> Deficient progress report
<input type="checkbox"/> Request waiver	<input type="checkbox"/> Manufacturing	<input type="checkbox"/> Deficient semi-annual report
<input type="checkbox"/> Termination of study	<input type="checkbox"/> Protocol - feasibility	<input type="checkbox"/> Disapproval
<input type="checkbox"/> Withdrawal of application	<input type="checkbox"/> Protocol - other	<input type="checkbox"/> Request extension of time to respond to FDA
	<input type="checkbox"/> Sponsor	<input type="checkbox"/> Request Meeting
<input type="checkbox"/> Emergency use:	<input type="checkbox"/> Report Submission:	<input type="checkbox"/> IOL submissions only:
<input type="checkbox"/> Notification of emergency use	<input type="checkbox"/> Semi-annual progress Manufacturer	<input type="checkbox"/> Change in IOL style
<input type="checkbox"/> Additional information	<input type="checkbox"/> Annual progress	<input type="checkbox"/> Request for protocol waiver
	<input type="checkbox"/> Unanticipated adverse effect	
<input type="checkbox"/> Other Reason (specify):	<input type="checkbox"/> Waiver/site limit	

Section F Manufacturing / Packaging / Sterilization Sites			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: (b)(4)	<input checked="" type="checkbox"/> Manufacturer/Sterilizer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name: (b)(4)			
Division name (if applicable): N/A		Phone number (include area code): (b)(4)	
Street address: (b)(4)		FAX number (include area code): (b)(4)	
City: (b)(4)	State / Province:	Country:	ZIP / Postal Code:
Contact name: (b)(4)			
Contact title: Quality Assurance Manager			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number:	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager/relabeler
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			

Section G Applicant or Sponsor			
Company / Institution name: Baxter Healthcare Corporation		FDA establishment registration number: 1416980	
Division name (if applicable): I.V. Systems Division		Phone number (include area code): (847) 270-4644	
Street address: Route 120 and Wilson Road		FAX number (include area code): (847) 270-4668	
City: Round Lake	State / Province: IL	Country: USA	ZIP / Postal Code: 60073
Signature: <i>Mary Ellen Snyder</i>			
Name: Mary Ellen Snyder			
Title: Manager, Regulatory Affairs			
Section H Submission correspondent (if different from above)			
Company / Institution name:			
Division name (if applicable):		Phone number (include area code): ()	
Street address:		FAX number (include area code): ()	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:			
Title:			

Baxter

April 9, 1998

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20855

**RE: 510(k) Premarket Notification
Dual Luer Lock Cap**

Dear Colleague:

This is to notify you of Baxter Healthcare Corporation's intention to manufacture and market a Dual Luer Lock Cap which will be used to cover standard male or female luer ports on medical devices.

To assist in your review of this 510(k) notification, we have completed a copy of FDA's "Premarket Notification 510(k) Checklist for Acceptance Decision"¹, and attached it to this submission (see Attachment 1.0 - 510(k) Checklist).

Product Description:

The subject of this submission is a sterile Dual Luer Lock Cap which will be used to cover male or female luer ports on medical devices. The proposed Dual Luer Lock Cap will replace the existing port cap on a number of currently marketed Baxter devices such as sets, stopcocks and manifolds. It will also be sold individually as a replacement cap to cover an open luer port after it has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end. Diagrams of the Dual Luer Lock Cap identifying components, materials and key dimensions are contained in Attachment 2.0 - Diagrams - Proposed Device. A diagram showing its use as a port cap on Baxter's marketed MultiPort Manifold is also provided in Attachment 2.0. A list of marketed Baxter devices which may substitute the proposed cap for the existing port cap along with the 510(k) numbers covering each product type is provided in Attachment 3.0 - Product List.

¹ Center for Devices and Radiological Health's Premarket Notification 510(k) Refuse to Accept Policy, June 30, 1993.

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10 Apr 98 13 13

FDA/CDRH/ODE/DMC

32

Baxter

Statement of Similarities and Differences to Marketed Devices:

The proposed Dual Luer Lock Cap is similar in design characteristics to several other marketed sterile replacement caps which feature a dual male/female luer connection. These include the Medex Male/Female Luer Lock Plug, the B. Braun Blue Cap Dual Function Luer Lock Plug and the Abbott Male/Female Sterile Cap. It is also similar to the existing port cap on Baxter's MultiPort Manifold. A matrix comparing the components and features of the proposed device to the marketed caps is provided in Attachment 4.0 - Comparison Chart. Samples of the proposed Dual Luer Lock Cap and competitive products are provided to facilitate review.

Materials:

There are no new materials involved in the proposed Dual Luer Lock Cap. The cap will be composed of (b)(4). This is the same material used to fabricate the current port protector on Baxter's marketed MultiPort Manifold. We certify that the materials to be used in the subject device are identical to materials used in legally marketed devices under comparable conditions of use.

Proprietary Name: Dual Luer Lock Cap

Common/Usual Name: Port Protector/Luer Cap

Classification Name: Intravascular Administration Set

Classification: Class II in 21CFR §880.5440

Classification Panel/Number: General Hospital and Personal Use Section of the
General Medical Device Panel/ 80 FPA

**Manufacturing/Sterilization Location and Establishment Registration
Number:**

(b)(4)

Owner/Operator Number: (b)(4)

Baxter

Performance Standard: None established under Section 514

Intended Use:

The Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

Performance Data:

Data regarding the functional performance of the proposed Dual Luer Lock Cap have been generated. A description of the functional testing along with test results is provided in Attachment 5.0 - Functional Testing. The data indicate that the proposed device meets or exceeds all functional requirements.

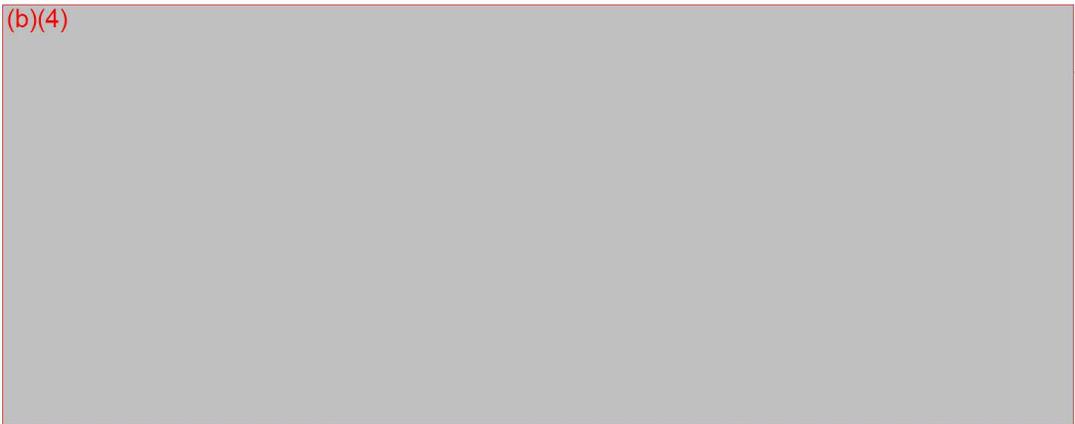
Labeling/Promotional Material:

Draft labeling for the proposed Dual Luer Lock Cap is provided in Attachment 6.0 - Draft Labeling.

Copies of labeling for the currently marketed Medex Male/Female Luer Lock Plug, B. Braun Blue Cap Dual Function Lock Lock Plug and the Abbott Male/Female Sterile Cap are provided in Attachment 7.0 - Marketed Device Labeling.

Packaging/Sterilization:

(b)(4)



Substantial Equivalence:

The proposed Dual Luer Lock Cap is substantially equivalent, for purposes of the Federal Food, Drug and Cosmetic Act only, to the B. Braun Blue Cap Dual Function Lock Lock Plug, Medex Male/Female Luer Lock Plug and the Abbott



Baxter

Male/Female Sterile Cap. We believe the B. Braun cap is covered by K820454, submitted by Burron Medical Products, Inc., and cleared 3/8/82. We believe the Medex Male/Female Luer Lock Plug is a preenactment device. This is evidenced by the 510(k) summary Medex prepared for K954970, Antimicrobial Luer Lock Plug, in which the Antimicrobial Luer Lock Plug is compared to the MX 491 Male/Female Luer Lock Plug described as a preenactment device. A copy of that 510(k) summary obtained from FDA's Internet site "Information on Releasable 510(k) summaries is provided in Attachment 8.0 - Medex Cap Preenactment Status. We were unable to locate a 510(k) number for the Abbott cap.

For your convenience, we have explained in Attachment 9.0 - SE Decision Tree, how we reached a substantial equivalence conclusion, using FDA's logic flow chart entitled "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)²".

The term substantial equivalence as outlined in this premarket notification and the supporting information pertaining to equivalence are intended only to demonstrate equivalence to predicate products for purposes of obtaining clearance of the device pursuant to the Federal Food, Drug and Cosmetic Act. Reference to equivalence as outlined in this submission is in no way related to the term "equivalent" or similar terminology as outlined under the patent laws.

Summary of Safety and Effectiveness:

A summary of safety and effectiveness of the proposed device, as required by the Safe Medical Devices Act of 1990, is provided in Attachment 10.0 - Summary of Safety and Effectiveness.

Truthful and Accurate Statement:

A certification statement as required by 21 CFR § 807.87 (j) is provided in Attachment 11.0 - Truthful and Accurate Statement.

Indication for Use:

In accordance with FDA requirements effective January 1, 1996, a separate page clearly marked Indication for Use is included as Attachment 12.0 - Indication for Use.

² FDA's Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30, 1993.

Baxter

If you have any questions regarding this submission, please do not hesitate to contact me. You may also contact Marcia Marconi, Vice President, Regulatory Affairs, at (847) 270-4637.

Sincerely,



Mary Ellen Snyder
Manager, Regulatory Affairs
(847) 270-4644
(847) 270-4668 FAX



Attachment 1.0

Premarket Notification 510(k) Checklist for Acceptance Decision

31

Premarket Notification (510(k) Checklist for Acceptance Decision

K: _____ **Date DMC Received:** _____

Device Trade Name: Dual Luer Lock Cap

Reason for 510(k): New Device

Division/Branch: Division of General and Restorative Devices/General Hospital Devices Branch

Administrative Reviewer Signature: _____ **Date:** _____

Supervisory Signature: _____ **Date:** _____

	Yes Present Omission Justified	No Inadequate Omitted
--	-----------------------------------	--------------------------

I. Critical Elements		
A. Is the product a device?	X	
B. Is the device exempt from 510(k) by regulation or policy?		X
C. Is device subject to review by CDRH?	X	
D. (i) Are you aware that this device has been the subject of a previous NSE decision? (ii) If yes, does this new 510(k) address the NSE issue(s) (e.g., performance data)?		X

Please Note: Information in parenthesis indicates where in the document items can be found.

	Yes Present Omission Justified	No Inadequate Omitted
--	-----------------------------------	--------------------------

<p>E. (i) Are you aware of the submitter being the subject of an integrity investigation? If yes, consult the ODE Integrity Officer</p> <p>(ii) Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N-0332, September 10, 1991.)</p>		X
<p>F. Does the submission contain the information required under Sections 510(k), 513(f), and 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) and Subpart E of Part 807 in Title 21 of the Code of Federal Regulations?:</p>	X	
<p>* Device trade or proprietary name</p>	X (cover letter)	
<p>* Device common or usual name or classification name</p>	X (cover letter)	
<p>* Establishment registration number (only applies if establishment is registered)</p>	X (cover letter)	
<p>* Class into which the device is classified under (21 CFR Parts 862 to 892)</p>	X (cover letter)	
<p>* Classification Panel</p>	X (cover letter)	
<p>* Action taken to comply with Section 514 of the Act</p>	X (cover letter)	

Please Note: Information in parenthesis indicates where in the document items can be found.

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	Yes Present Omission Justified	No Inadequate Omitted
* Proposed labels, labeling and advertisements (if available) that describe the device, its intended use, and directions for use(Blue Book Memo#G91-1)	X (Attachment 6.0)	
* A 510(k) summary of safety and effectiveness or a 510(k) statement that safety and effectiveness information will be made available to any person upon request	X (Attachment 10.0)	
* For class III devices only, a class III certification and a class III summary	N/A	
* Photographs of the device (Drawings of the Device are provided)	X (Attachment 2.0)	
* Engineering drawings for the device with dimensions and tolerances (Drawings of the device in Attachment 2.0 contain key dimensions and tolerances)	X (Attachment 2.0)	

Please Note: Information in parenthesis indicates where in the document items can be found.

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	Yes Present Omission Justified	No Inadequate Omitted
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* The marketed device(s) to which equivalence is claimed including labeling and description of the device	X (Cover Letter; Attachment 7.0)	
* Statement of similarities and/or differences with marketed device(s)	X (Cover Letter)	
* Data to show consequences and effects of a modified device	X (Attachment 5.0)	
II. Additional Information that is necessary under 21 CFR 807.87(h):		
A. Submitter's name and address	X (cover letter)	
B. Contact person, telephone number and fax number	X (cover letter)	
C. Representative/Consultant if applicable	N/A	
D. Table of Contents with pagination	X	
E. Address of manufacturing facility/facilities and, if appropriate, sterilization site(s)	X (cover letter)	

Please Note: Information in parenthesis indicates where in the document items can be found.

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	Yes Present Omission Justified	No Inadequate Omitted
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III. Additional Information that <u>may be</u> necessary under 21 CFR 807.87(h):		
A. Comparison table of the new device to the marketed device(s)	X (Attachment 4.0)	
B. Action taken to comply with voluntary standards	N/A	
C. Performance data marketed device		
bench testing	N/A	
animal testing	N/A	
clinical data	N/A	
New device		
bench testing	X (Attachment 5.0)	
animal testing	N/A	
clinical data	N/A	
D. Sterilization information	X (cover letter)	
E. Software information	N/A	
F. Hardware information	N/A	

Please Note: Information in parenthesis indicates where in the document items can be found.

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	Yes Present Omission Justified	No Inadequate Omitted
<p>G. Is this device subject to issues that have been addressed in specific guidance document(s)?</p> <p>If yes, continue review with checklist from any appropriate guidance documents.</p> <p>If no, is 510(k) sufficiently complete to allow substantive review?</p>	X	X
<p>H. Other (specify)</p>		

Please Note: Information in parenthesis indicates where in the document items can be found.

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Attachment 2.0

Diagrams - Proposed Device

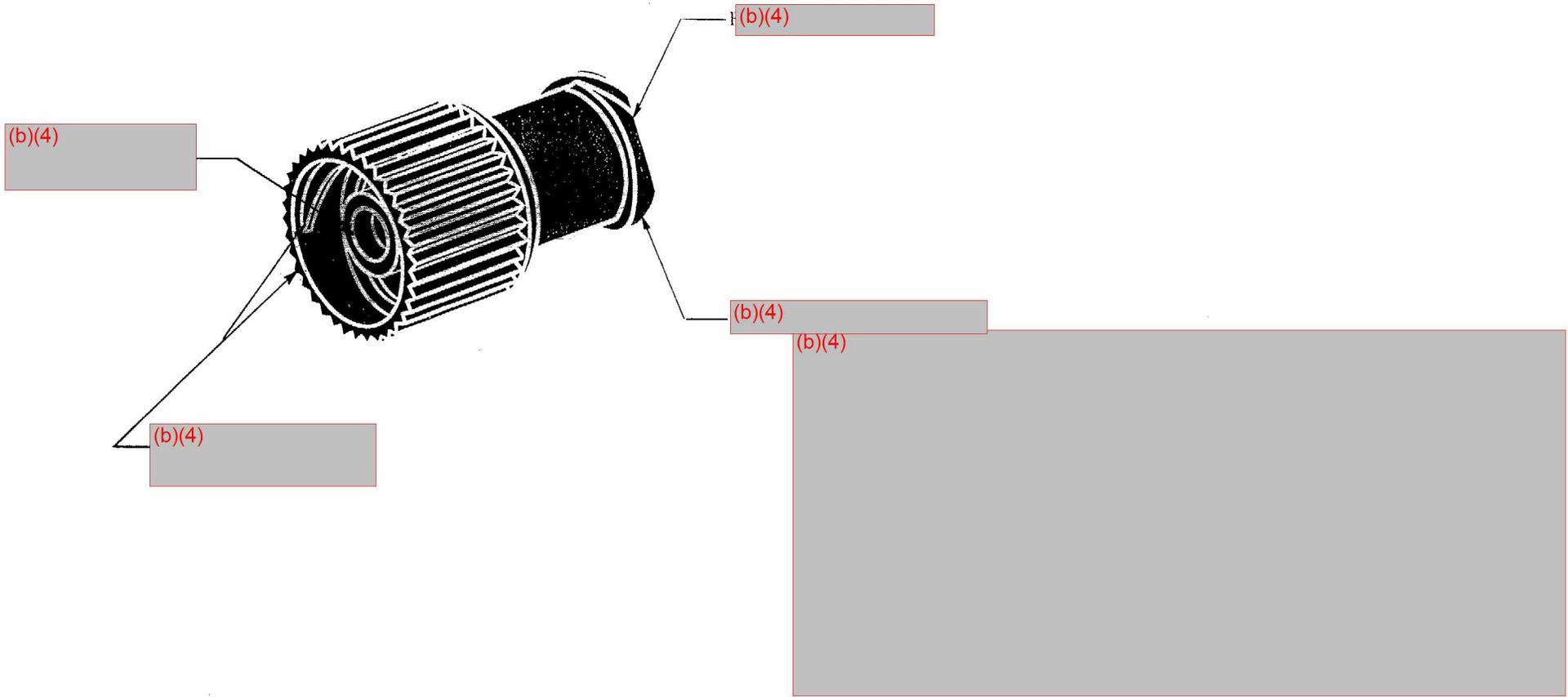


Attachment 2.1

Diagram of Components, Materials and Key Dimensions
Proposed Dual Luer Lock Cap

Raw Material:

(b)(4)



Attachment 2.2

Diagram of Baxter MultiPort Manifold¹ with
Proposed Dual Luer Lock Cap

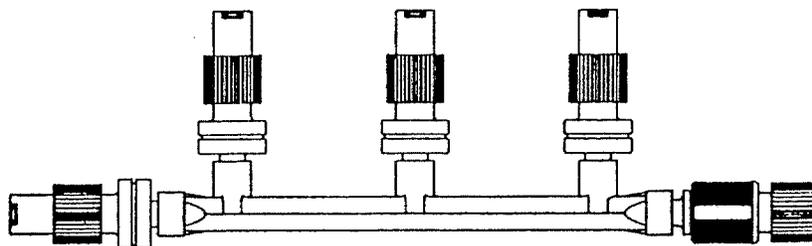
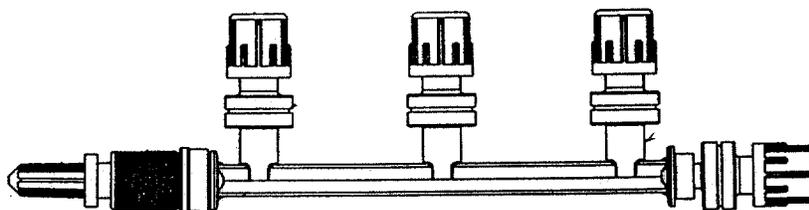


Diagram of Baxter MultiPort Manifold¹ with
Current Port Protectors



¹ Baxter's MultiPort Manifold is covered by K932512, cleared 2/22/94

A handwritten signature or initials, possibly 'Jb', located in the bottom right corner of the page.

Attachment 3.0

Product List



ATTACHMENT 3.0
PRODUCT LIST

As mentioned previously, Baxter plans to substitute the port protectors on a number of currently marketed devices with the proposed Dual Luer Lock Cap. A list of representative device types which Baxter intends to introduce with this change is provided below along with the previously cleared 510(k) submission numbers covering the device.

<u>Device Type</u>	<u>Applicable 510(k) Numbers</u>
MultiPort Manifold	K932512
Solution Sets with Multi-Port Manifold	K932512, K961225
Stopcocks and Stopcock Manifold Gangs	K955782
Extension Sets	K811078, K915390, K921899
3 Port Adapter	K913627

Attachment 4.0

Comparison Chart

Handwritten initials, possibly 'JP', in the bottom right corner.

Attachment 4.0

Comparison Chart

Component or Feature	Baxter Dual Luer Lock Cap	Baxter MultiPort Manifold Cap	Medex Male/Female Luer Lock Plug	B. Braun Dual Function Luer Lock Plug	Abbott Male/Female Sterile Cap
Intended Use	Capping standard luer adapters	Capping standard luer adapters	Capping standard luer adapters	Capping standard luer adapters	Capping standard luer adapters
Compatible with standard¹ male and female luer adapters	Yes	No - Compatible with standard female luers only	Yes	Yes	Yes
Integrated Male/Female Design	Yes	No - One part for female luers only	Yes	Yes	No - Two separate parts
Male Post Geometry	Short Post	Long Post	Short Post	Short Post	Short Post
Female Luer Lock	Full Thread	N/A	Full Thread	Full Thread	Lugs
Knurled or Ribbed Grip Surface	Knurled	Ribbed	Knurled	Knurled	Ribbed
Material	(b)(4)				
Latex - Free	Yes	Yes	Yes	Yes	Yes

¹ Caps are designed to fit male/female luer adapters whose dimensions meet ANSI/HIMA MD 70.1-1983 standards

Attachment 5.0

Functional Testing



ATTACHMENT 5.0
SUMMARY OF FUNCTIONAL TESTING
PROPOSED DUAL LUER LOCK CAP

TEST	FUNCTIONAL REQUIREMENTS	RESULTS
(b)(4)		

TEST DESCRIPTION/CONDITIONS:

(b)(4)

Attachment 6.0

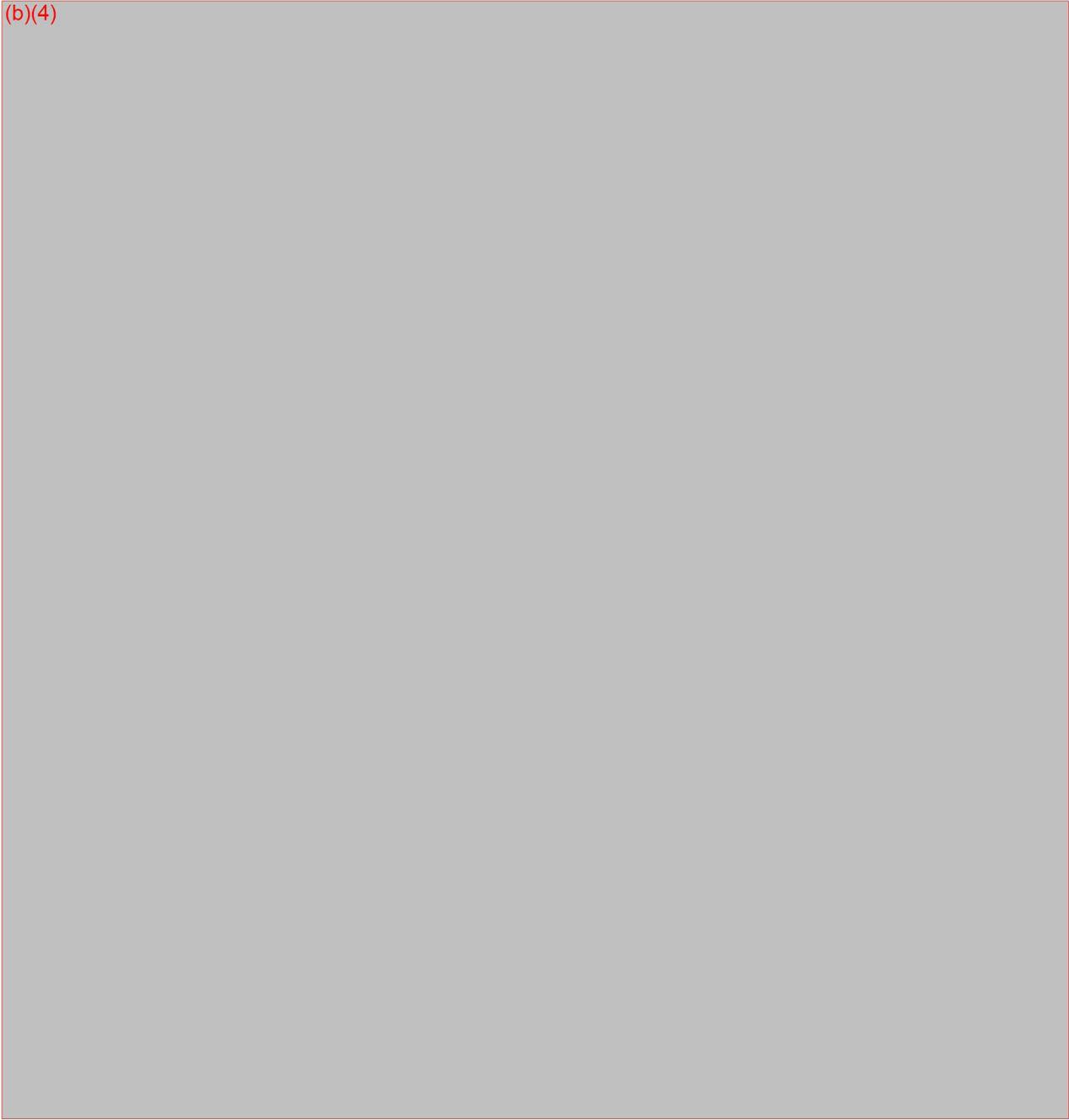
Draft Labeling - Proposed Device

SB

Attachment 6.0

Draft Labeling- Direction Sheet and Unit Label

(b)(4)



sd

Attachment 7.0

Marketed Device Labeling



Attachment 7.1

Marketed Device Labeling
Medex Male/Female Luer Lock Plug
Carton and Unit Label



STERILE

PRODUCT#:

MX491B

MALE/FEMALE L.L. PLUG (BLUE)
WITH RECESSED MALE



+H365MX491B3Q



+#27L011273QL

CASE QTY: 100

LOT#: 27L011273

medex inc. HILLIARD, OHIO 43026 U.S.A. MX491B medex inc. HILLIARD, OHIO 43026 U.S.A. RECESSED MLL PLUG B

STERILE AND NON-PYROGENIC UNLESS PACKAGE IS DAMAGED OR OPENED. SINGLE USE. Caution: Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.

STERILE AND NON-PYROGENIC UNLESS PACKAGE IS DAMAGED OR OPENED. SINGLE USE. Caution: Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.

STEP

Attachment 7.2

Marketed Device Labeling
B. Braun Blue Cap Dual Function Luer Lock Plug
Carton and Unit Label

Blue Cap

dual function luer lock plug for capping male or female luer adapters.

-compatible

Contents of unopened, undamaged individual packages are: Sterile, non-pyrogenic.

100 Caps

B|BRAUN

Disposable. Destroy after single use. Do not clean or resterilize.

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

B. Braun Medical Inc.
Bethlehem, PA 18018
Made in Germany

Product Code:
100 Caps

B2000
654493

Product Code:
1000 Caps

B2000B
654491

Lot No.: 97J0199-01022

Exp.: 2002-10
Sterile

1242364/5

sterile disposable disposable disposable dispo
genic Sterile - Non-pyrogenic Sterile - Non-pyro
er Lock Plug Luer Lock Plug Luer Lock Plug Lu
sable Disposable Disposable Disposable Dispo:
genic Sterile - Non-pyrogenic Sterile - Non-pyro
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sable Disposable Disposable Disposable Dispo:
genic Sterile - Non-pyrogenic Sterile - Non-pyro
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00854491

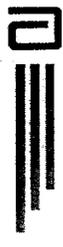
A4802840 P-1193-3 Rev. 1/96

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Attachment 7.3

Marketed Device Labeling
Abbott Male/Female Sterile Cap
Direction Sheet and Unit Label

120 Units/No. 11477

 LifeShield® LATEX-FREE
**MALE/FEMALE
STERILE CAP**
For Capping of Male or
Female Luer Adapters



USE ASEPTIC TECHNIQUE

For use in capping standard male or female luer adapters.

- Connect cover to adapter (male or female).
- Tighten by turning clockwise.

Sterile and nonpyrogenic in intact unit package.
Do not store at extreme temperatures.
Disposable device. Do not resterilize or reuse.

This device should be changed per CDC
guidelines or health care provider policy.
Discard after use.

Caution: Federal (USA) law restricts this device
to sale by or on the order of a physician or other
licensed practitioner.

Product inquiries should be directed to Abbott
Laboratories, North Chicago, IL 60064, USA

 LifeShield® LATEX-FREE One/No. 11477
MALE/FEMALE STERILE CAP
See insert.
Product inquiries should be directed to
Abbott Laboratories, North Chicago, IL 60064, USA 98-4068-R1-10/96
Printed in USA
Lot **38004HG01**



©Abbott 1996

06-9462-R2-10/96

Printed in USA



Attachment 8.0

**Evidence of Preenactment Status
Medex Dual Function Luer Lock Cap**





510(k) Summary

K 75 49 10

APR 22 1996

K 95 49 70

This summary regarding 510(k) safety and effectiveness and being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

§ 807.92 (a)(1) Submitter's (and Contact) Names, Address, Telephone No., Summary Date

- John Toomey
Senior Project Engineer
Medex, Inc.
6250 Shier-Rings Road
Dublin, Ohio 43017
(614) 791 5415

- 10.20.95

§ 807.92 (a)(2) Device Name (Including Trade Name), Common Name, Classification Name

- MX531-1LT Antimicrobial IV Set Stopcock and MX491T Antimicrobial Luer Lock Plug
- Stopcock and Luer Lock Plug
- Stopcock, I-V Set

§ 807.92 (a)(3) Legally Marketed Predicate Device to Which Equivalence is Claimed

- Medex, Inc.'s pre-amendment stopcock and Luer lock plug MX531-1L and MX491, respectively. *

- Additionally, the modified devices use a substantially equivalent technology as the Vitaphore Corporation's VitaGuard® Percutaneous Infection Control Kit (K861563).

§ 807.92 (a)(4) Description of the Premarket Notification Device

- The Medex, Inc. antimicrobial stopcock and Luer lock plug are functionally conventional devices, which incorporate antimicrobial properties through the addition of a elemental, metallic silver additive.
- The materials which comprise the MX531-1LT and MX491T have been aggressively tested per the ANSI/AAMI/ISO 10993 "Biological Evaluation of Medical Devices" and the "Tripartite Biocompatibility Guidance for Medical Devices". All materials have successfully met these standards.

§ 807.92 (a)(5) Intended Use

- A stopcock is a typical element of fluid or drug administration. It is used to control/direct fluid flow and permit fluid access to the patient. A Luer lock plug is used to terminate any open Luer port.

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Attachment 9.0

Substantial Equivalence Decision Tree

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Dual Luer Lock Cap
510(k) "Substantial Equivalence" Decision Making Process

Baxter Healthcare Corporation proposes to market a Dual Luer Lock Cap which will be used to cover standard male or female luer ports on medical devices. The proposed cap will replace the existing port cap on a number of currently marketed Baxter devices such as manifolds, stopcocks and sets. It will also be sold individually as a replacement cap to cover an open luer port after it has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end.

Using the logic flow chart entitled "510(k) 'Substantial Equivalence' Decision-Making Process (Detailed)¹," we explain how we attained a "Substantial Equivalence" conclusion. A copy of the flow chart, with the decision path highlighted, appears at the end of this attachment.

New Device is Compared to Marketed Devices:

Does New Device Have Same Indication Statements?

Yes. The proposed device has the same intended use as the predicate device. The Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

New Device has Same Intended Use and May be "Substantially Equivalent"

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

Yes. The proposed Dual Luer Lock Cap is similar in design characteristics to several other marketed sterile replacement caps which feature a dual male/female luer connection. These include the Medex Male/Female Luer Lock Plug, the B. Braun Blue Cap Dual Function Lock Lock Plug and the Abbott Male/Female Sterile Cap. It is also similar to the existing port cap on Baxter's MultiPort Manifold. A matrix comparing the components and features of the proposed device to the marketed caps is provided in **Attachment 4.0 - Comparison Chart**.

There are no new materials involved in the proposed device. It is comprised of the same material used to fabricate the current port protector on Baxter's marketed MultiPort Manifold covered by K932512.

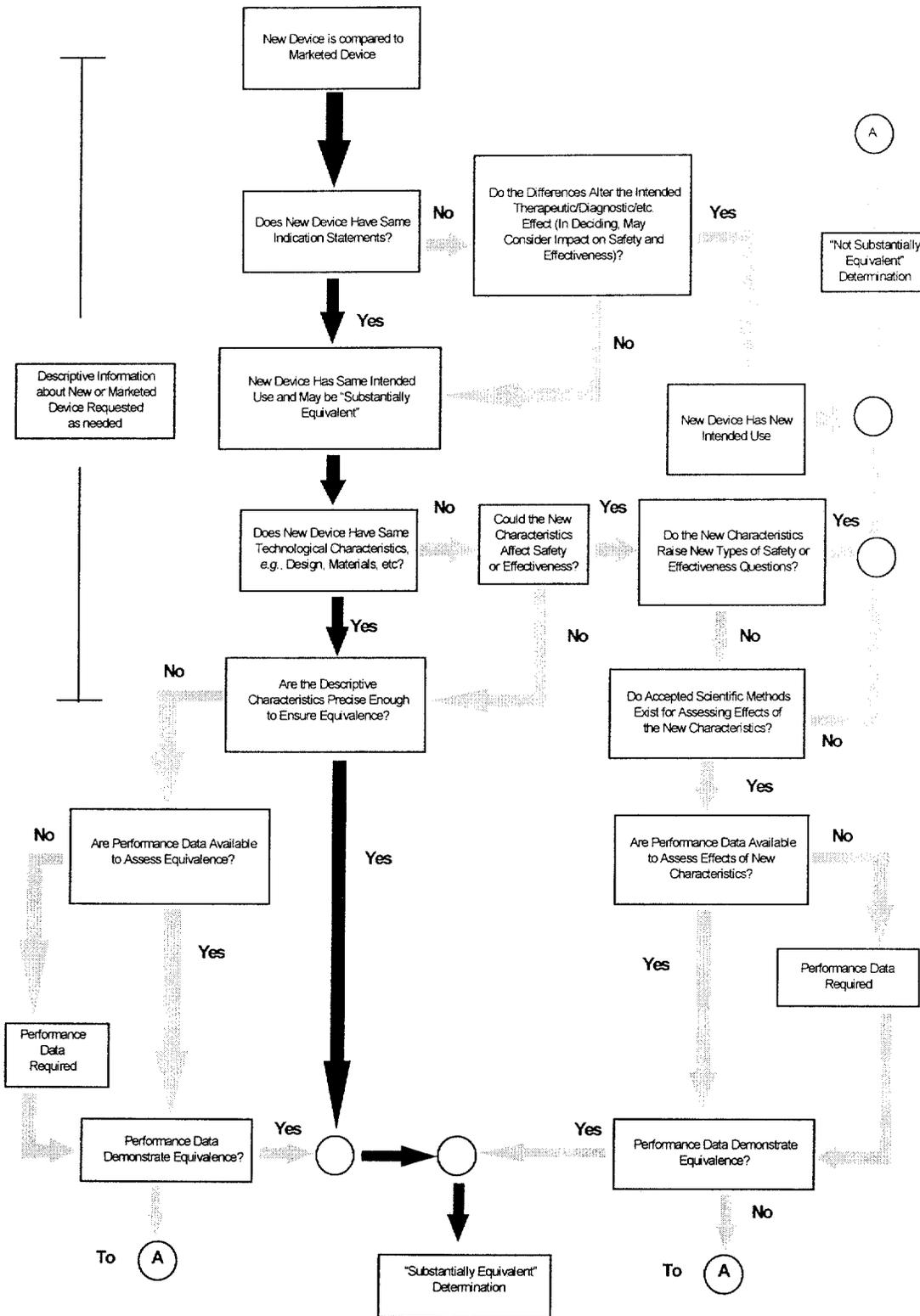
¹ FDA's Guidance on the Center for Devices and Radiological Health's Premarket Notification Review Program, June 30, 1986.

Are the Descriptive Characteristics Precise Enough to Ensure Equivalence?

Yes. In this 510(k) submission, the product similarities and difference to marketed devices are summarized in the cover letter and in **Attachment 4.0 - Comparison Chart**. Functional testing has been performed and data is provided in **Attachment 5.0 - Functional Testing**. Performance data indicate that the proposed cap meets or exceeds all functional requirements and support its suitability for use.

“Substantially Equivalent” Determination

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



bcf

Attachment 10.0

Summary of Safety and Effectiveness

LS

510(k) SUMMARY

Dual Luer Lock Cap

Submitted by:

Mary Ellen Snyder
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:

April 9, 1998

Proposed Device:

Dual Luer Lock Cap

Predicate Device:

Medex Male/Female Luer Lock Plug
B. Braun Blue Cap Dual Function Lock Lock Plug
Abbott Male/Female Sterile Cap

Proposed Device Description:

The subject of this submission is a sterile Dual Luer Lock Cap which will be used to cover male or female luer ports on medical devices. The proposed Dual Luer Lock Cap will replace the existing port cap on a number of currently marketed Baxter devices such as sets, stopcocks and manifolds. It will also be sold individually as a replacement cap to cover an open luer port after it has been accessed and is no longer in use. The Dual Luer Lock Cap consists of an integrated design with a male luer lock connection on one end and a female luer lock connection on the other end.

Statement of Intended Use:

The Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

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Summary of Technological Characteristics of New Device to Predicate Devices

The proposed Dual Luer Lock Cap is similar in design characteristics to several other marketed sterile replacement caps which feature a dual male/female luer connection. These include the Medex Male/Female Luer Lock Plug, the B. Braun Blue Cap Dual Function Lock Lock Plug and the Abbott Male/Female Sterile Cap. It is also similar to the existing port cap on Baxter's MultiPort Manifold.

There are no new materials involved in the proposed device. It is comprised of the same material used to fabricate the current port protector on Baxter's marketed MultiPort Manifold.

Discussion of Nonclinical Tests and Referenced Studies Reported in Published Literature

Data regarding the functional performance of the proposed Dual Luer Lock Cap have been generated. A description of the functional testing along with test results has been provided. The data indicate that the proposed cap meets or exceed all functional requirements and support its suitability for use.

Attachment 11.0

Truthful and Accurate Statement

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

I certify that, in my capacity as Manager, Regulatory Affairs of Baxter Healthcare Corporation, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.



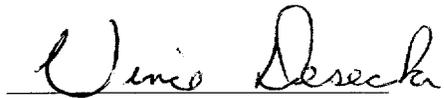
Mary Ellen Snyder

Manager, Regulatory Affairs, I.V. Systems Division

4/6/98

Date

I certify that, in my capacity as Senior Engineering Specialist of Baxter Healthcare Corporation, I believe, to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.



Vince Desecki

Senior Engineering Specialist, Access Systems

4-6-98

Date

Attachment 12.0

Indication for Use

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510(k) Premarket Notification
Dual Luer Lock Cap

510(k) Number: Not Available

Device Name: Dual Luer Lock Cap

Indication for Use:

Baxter's Dual Luer Lock Cap is intended for use as a cap for male or female luer ports on medical devices such as manifolds, stopcocks or sets.

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