

APR 10 2003

K023872

510(k) Summary

Submitter:

VitalCare
15800 NW 13th Avenue
Miami Fl. 33169

Contact:

Michael McAvenia
Director of Quality Assurance
(305) 620-4007
Fax: (305) 620-5220
Internet: michaelm@vitalcare.com

Name of Device:

VitalCare Urethral Catheter Red Rubber

Predicate Device:

Kendall Dover Red Rubber Robinson Catheter

Description of the New Device:

Urethral Catheter Red Rubber

Intended Use of the New Device:

VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

Comparison of the Technological Features of the New Device and Predicate Device:

The new device features and predicate features are similar. The design, materials used for the catheter and pouch and labeling of the pouch are similar.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 1 0 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael McAvenia
Director of Quality Assurance
Vital Care, Inc.
15800 NW 13th Avenue
MIAMI FL 33169

Re: K023872
Trade/DeviceName: VitalCare Urethral
Catheter Red Rubber
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter
and accessories
Regulatory Class: II
Product Code: 78 EZD and GBM
Dated: February 25, 2003
Received: February 27, 2003

Dear Mr. McAvenia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

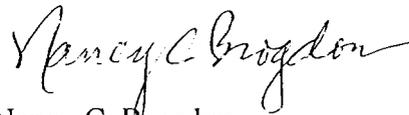
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|----------------------------------|----------------|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023872

INDICATIONS FOR USE

510(k) Number: K023872

Device Name: Urethral Catheter Red Rubber

Indications for Use: VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David H. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K023872

Prescription Use
(Per 21 CFR 801.109)

15023872/AI

510(k) Summary

Submitter:

VitalCare
15800 NW 13th Avenue
Miami Fl. 33169

Contact:

Michael McAvenia
Director of Quality Assurance
(305) 620-4007
Fax: (305) 620-5220
Internet: michaelm@vitalcare.com

FDA/CDRH/OCE/DID
2013 JUN 12 A 10:04

Name of Device:

VitalCare Urethral Catheter Red Rubber

Predicate Device:

Kendall Dover Red Rubber Robinson Catheter

Description of the New Device:

Urethral Catheter Red Rubber

Intended Use of the New Device:

VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

Comparison of the Technological Features of the New Device and Predicate Device:

The new device features and predicate features are similar. The design, materials used for the catheter and pouch and labeling of the pouch are similar.

513 10

JUPPLICATE

510(k) Summary

Submitter:

VitalCare
15800 NW 13th Avenue
Miami Fl. 33169

Contact:

Michael McAvenia
Director of Quality Assurance
(305) 620-4007
Fax: (305) 620-5220
Internet: michaelm@vitalcare.com

Name of Device:

VitalCare Urethral Catheter Red Rubber

Predicate Device:

Kendall Dover Red Rubber Robinson Catheter

Description of the New Device:

Urethral Catheter Red Rubber

Intended Use of the New Device:

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Comparison of the Technological Features of the New Device and Predicate Device:

The new device features and predicate features are similar. The design, materials used for the catheter and pouch and labeling of the pouch are similar.

**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

I certify as a responsible representative of VitalCare that I believe to the best of my knowledge and understanding, all data and information submitted in this Premarket notification are truthful and accurate and that no material fact has been omitted.



3-10-03

Michael McAvenia
Director of Quality Assurance
VitalCare Group, Inc

Date

Premarket Notification [510(k)] Number



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 10 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael McAvenia
Director of Quality Assurance
Vital Care, Inc.
15800 NW 13th Avenue
MIAMI FL 33169

Re: K023872
Trade/DeviceName: VitalCare Urethral
Catheter Red Rubber
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter
and accessories
Regulatory Class: II
Product Code: 78 EZD and GBM
Dated: February 25, 2003
Received: February 27, 2003

Dear Mr. McAvenia:

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If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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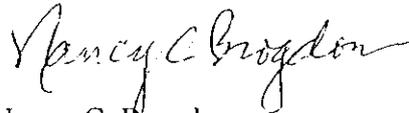
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

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| Other | (301) 594-4692 |

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Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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K023872

INDICATIONS FOR USE

510(k) Number: K023872

Device Name: Urethral Catheter Red Rubber

Indications for Use: VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

Concurrence of CDRH, Office of Device Evaluation (ODE)

David H. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K023872

Prescription Use
(Per 21 CFR 801.109)

3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

March 06, 2003

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

VITALCARE, INC.
15800 NW 13TH AVENUE
MIAMI, FL 33169
ATTN: MICHAEL MCAVENIA

510(k) Number: K023872
Product: VITALCARE
URETHRAL
CATHETER RED
RUBBER

The additional information you have submitted has been received.

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

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

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

Sincerely yours,

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

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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)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

February 05, 2003

VITALCARE, INC.
 15800 NW 13TH AVENUE
 MIAMI, FL 33169
 ATTN: MICHAEL MCAVENIA

510(k) Number: K023872
 Product: VITALCARE
 URETHRAL
 CATHETER RED
 RUBBER

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. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete 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 your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

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

Sincerely yours,

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

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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)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

November 21, 2002

VITALCARE, INC.
 15800 NW 13TH AVENUE
 MIAMI, FL 33169
 ATTN: MICHAEL MCAVENIA

510(k) Number: K023872
 Received: 20-NOV-2002
 Product: VITALCARE URETHRAL
 CATHETER RED RUBBER

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

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

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

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

Sincerely yours,

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

5023872

March 27, 2002

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

Re: Traditional 510(k) Notification for the VitalCare Urethral Catheter Red Rubber

Dear Document Control Clerk:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention VitalCare, 15800 NW 13th Avenue, Miami, FL 33169 to introduce into the market place various sizes of individually packaged, Sterile, Single-Use Urethral Catheter Red Rubber.

RECEIVED
2002 NOV 20 PM 3:52
FDA/CDRH/ODE/PRO

Labels and labeling for the device are enclosed. A detailed description of the similarities to the Kendall Dover Red Rubber Robinson Catheter, currently being distributed, is the basis for which the substantial equivalence determination is made content of this 510(k)

In response to requirements of the SMDA of 1990, included is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

This 510(k) Notification is formatted as outline in the guidance document "Pre-market Notification 510(k): Regulatory requirements for Medical Devices, 95-4158." Additionally, an annotated copy of the checklist from the March, 1995 document "Center for Devices and Radiological Health's Pre-market Notification for 510(k) Refuse to Accept Checklist" is provided.

Should you require additional information, please do not hesitate to contact the undersigned at (305) 6204007. An E-mail message may be sent to michaelm@vitalcare.com. My mailing address is 15800 NW 13th Avenue, Miami, FL 33169.

Sincerely,



Michael McAvenia
Director of Quality Assurance

Contents: 510(k) Notification-Original and one copy

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Table of Contents

Part A: Cover Letter.

Part B: Table of Contents.

Part C: Checklist for Acceptance.

Part D: Checklist for 510(k) Summary.

Part E: 510(k) Summary.

Part F: Certifications.

1. Truthful and Accurate Statement.
2. Indications For Use.

Part G: Submitter Information

1. Applicant.
2. Contact Person.
3. Representative/Consultant.
4. Establishment Number.
5. Address of Manufacturing Site.

Part H: Description of the VitalCare Urethral Catheter Red Rubber

1. Device Trade or Proprietary Name.
2. Device Common and classification Name(s).
3. Classification Information.
4. Description of the New Device.
 - a. Type of Device.

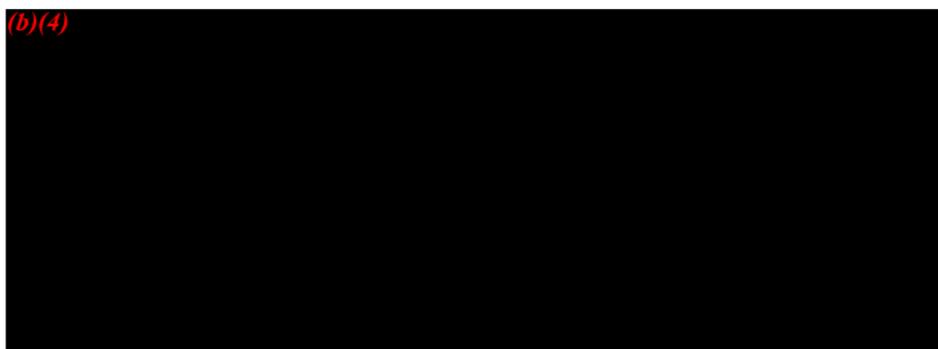
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- b. Statement of intended use.
 - c. Use with other devices.
 - d. Physical Specifications
 - i. Components and Materials.
 - ii. Other materials.
 - iii. Power requirements.
 - iv. Nominal dimensions.
 - e. Mechanical Specifications.
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 - i. ISO 10993 determination.
 - ii. Biocompatibility evaluations.
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 - ii. Stability requirements
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- a. Package labels
 - b. Instructions for Use
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7. Engineering Drawings
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- a. Bench Data
 - b. Comparative Data
 - c. Unique Designs

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- d. Biocompatibility Data
- e. Drug/Device Compatibility
- f. Drug Stability

11. Sterilization Information



- 12. Software Information
- 13. Hardware Information
- 14. Kit Certification statement
- 15. Guidance document issues

Part I. Description of the Kendall Dover Urethral Robinson Catheter

- 1. Device Trade or Proprietary Name
- 2. Device Common and Classification Name(s)
- 3. Classification Information
- 4. Document Control Number
- 5. Description of the Marketed Equivalent Device
 - a. Type of Device
 - b. Use with other devices
 - c. Physical Specifications
 - i. Components and materials
 - ii. Power Requirements
 - iii. Nominal Dimensions

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- d. Mechanical Specifications
- e. Biological Specifications
- f. Chemical Specifications
 - i. Compatibility requirements
6. Intended Use of the Marketed Equivalent Device
7. Labels and Labeling.

Part J. Comparison of the New and existing Devices

1. Similarities
2. Differences
3. Table of Comparison

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1. Specifications
2. Qualification Test Report
3. Labels
 - a. Box
 - b. Pouch
4. Labeling
5. Engineering Reports
6. Photographs

Q8

Checklist for Acceptance

| Question | Yes | No | Page |
|--|-----|----|------|
| A. Critical Elements | | | |
| 1. Is the product a device? | ✓ | | |
| 2. Is the device exempt from 510(k) by regulation or policy? | | ✓ | |
| 3. Is the device subject to review by CDRH? | ✓ | | |
| 4. Are you aware of this device being the subject of a previous NSE decision? | | ✓ | |
| 5. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ | |
| 6. Does the submission contain the information required? | ✓ | | |
| Device Trade Name | ✓ | | |
| Device Common Name | ✓ | | |
| Establishment registration name | ✓ | | |
| Device classification | ✓ | | |
| Classification Panel | ✓ | | |
| Section 514 action | | ✓ | |
| Proposed Labels, labeling | ✓ | | |
| 510(k) Summary | ✓ | | |
| Photographs/drawings of the device | ✓ | | |
| Engineering drawings | ✓ | | |
| Labeling of predicate | ✓ | | |
| Statement of similarities and or differences | ✓ | | |
| Data re: modified device | | ✓ | |
| Truthful and Accurate Statement | ✓ | | |
| Indications for Use Statement | ✓ | | |
| B. Additional Necessary Information | | | |
| 1. Submitter's name/address | ✓ | | |
| 2. Contac Person Information | ✓ | | |
| 3. Representative/Consultant | ✓ | | |
| 4. Table of Contents | ✓ | | |
| 5. Address of Mfg. facility | ✓ | | |
| C. Additional Information | | | |
| 1. Comparison table | ✓ | | |
| 2. Voluntary Standards Action | | ✓ | |
| 3. Performance Data | ✓ | | |
| 4. Sterilization Data | ✓ | | |

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| | | | |
|---|---|---|--|
| 5. Software Information | | ✓ | |
| 6. Hardware Information | | ✓ | |
| 7. Kit certification statement | | ✓ | |
| 8. Guidance document issues | | ✓ | |
| D. 510(k) Summary Checklist | | | |
| 1. Separate section of the submission | ✓ | | |
| 2. Submitter information, date | ✓ | | |
| 3. Identification of new device | ✓ | | |
| 4. Identification of predicate device | ✓ | | |
| 5. Description of new device | ✓ | | |
| 6. Intended Use of new device | ✓ | | |
| 7. Summary of comparison of technological characteristics | ✓ | | |
| 8. Discussion of nonclinical data, if any | | ✓ | |
| 9. Conclusions from clinical/nonclinical studies, if any | | ✓ | |
| 10. Contents of summary | | | |
| a. All information is contained in the submission | ✓ | | |
| b. No unsubstantiated labeling claims | | ✓ | |
| c. No raw data; only summaries | | ✓ | |
| d. No trade secret/confidential information | | ✓ | |
| e. No patient identification information | | ✓ | |

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510(k) Summary

Submitter:

VitalCare
15800 NW 13th Avenue
Miami Fl. 33169

Contact:

Michael McAvenia
Director of Quality Assurance
(305) 620-4007
Fax: (305) 620-5220
Internet: michaelm@vitalcare.com

Name of Device:

VitalCare Urethral Catheter Red Rubber

Predicate Device:

Kendall Dover Red Rubber Robinson Catheter

Description of the New Device:

Urethral Catheter Red Rubber

Intended Use of the New Device:

VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract. The number of days to remain indwelling is less than 30 days based on accepted hospital protocol.

Comparison of the Technological Features of the New Device and Predicate Device:

The new device features and predicate features are similar. The design, materials used for the catheter and pouch and labeling of the pouch are similar.

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**PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT**

I certify as a responsible representative of VitalCare that I believe to the best of my knowledge and understanding, all data and information submitted in this Premarket notification are truthful and accurate and that no material fact has been omitted.

Michael McAvenia
Director of Quality Assurance
VitalCare Group, Inc

Date

Premarket Notification [510(k)] Number

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INDICATIONS FOR USE

510(k) Number:

Device Name: Urethral Catheter Red Rubber

Indications for Use: VitalCare's Urethral Catheter Red Rubber is intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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SUBMITTER INFORMATION

- 1. Applicant:** VitalCare
15800 NW 13th Avenue
Miami Fl. 33169
- 2. Contact Person:** Michael McAvenia
Director of Quality Assurance
(305) 620-4007
Fax: (305) 620-5220
Internet: michaelm@vitalcare.comVitalCare
- 3. Establishment Registration
Number:**1063200
- 4. Address of Manufacturing Site:** Well Lead Medical Instruments CO., LTD.
Panyu, Guangzhou, P.R. China

All devices manufactured in China will be clearly labeled as such.

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Description of the New Device

1. **Device Trade or Proprietary name:**

VitalCare Urethral Catheter Red Rubber

2. **Device Common and Classification Name(s):**

Common Name: Urethral Catheter Red Rubber

Classification Name: Catheter, Urethral

3. **Classification Information:**

Class: Class II

Panel: Gastroenterology

Product Code: GBM

Cite: 21 CFR 876.5130

4. **Description of the New Device:**

a. **Type of Device:** VitalCare Urethral Catheter Red Rubber is a single use, flexible tubular device. The proximal end of the catheter contains two opposing fenestrations designed to facilitate drainage from the bladder, the catheter is designed to facilitate attachment of the Urethral Catheter to an external urinary collection system to maintain a closed system.

b. **Statement of intended Use:**

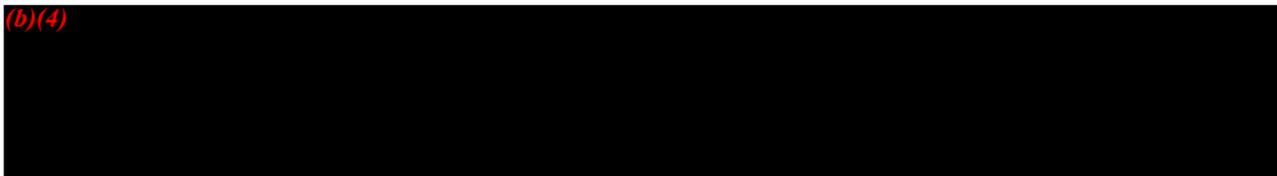
VitalCare's Urethral Catheter Red Rubber are intended to be inserted through the urethra to the bladder and utilized for passage of fluid from the urinary tract.

c. **Use with other devices:**

VitalCare's Urethral Catheter Red Rubber is designed to be used with urine collection devices and accessories.

d. **Physical specifications:**

(b)(4)



Part Description

Material



ii. Other Materials: N/A

iii. Power Requirements: N/A

iv. Nominal Dimensions: 8F, 10F, 12F, 14F, 16F, 18F, 20F and 22F X 398mm long.

e. Mechanical Specifications:

In accordance with ASTM F 623-99

f. Biological Specifications:

i. ISO 10993 determination

ii. Biocompatibility determination in accordance with ISO 10993

g. Chemical Specifications:

i. Compatibility requirements

ii. Stability requirements

h. Product Specification: The product engineering specification is included in Appendix 1. The Qualification Test Plan for the device is included in Appendix 2.

5. Labels, Labeling and Advertisements

a. Package labels: Copies of the sterile pack and box labels for the device are included in Appendix 3.

b. Instructions for Use: A copy of the device Instructions for Use are included in Appendix 4.

c. Promotional Materials: No promotional materials have been developed for this device.

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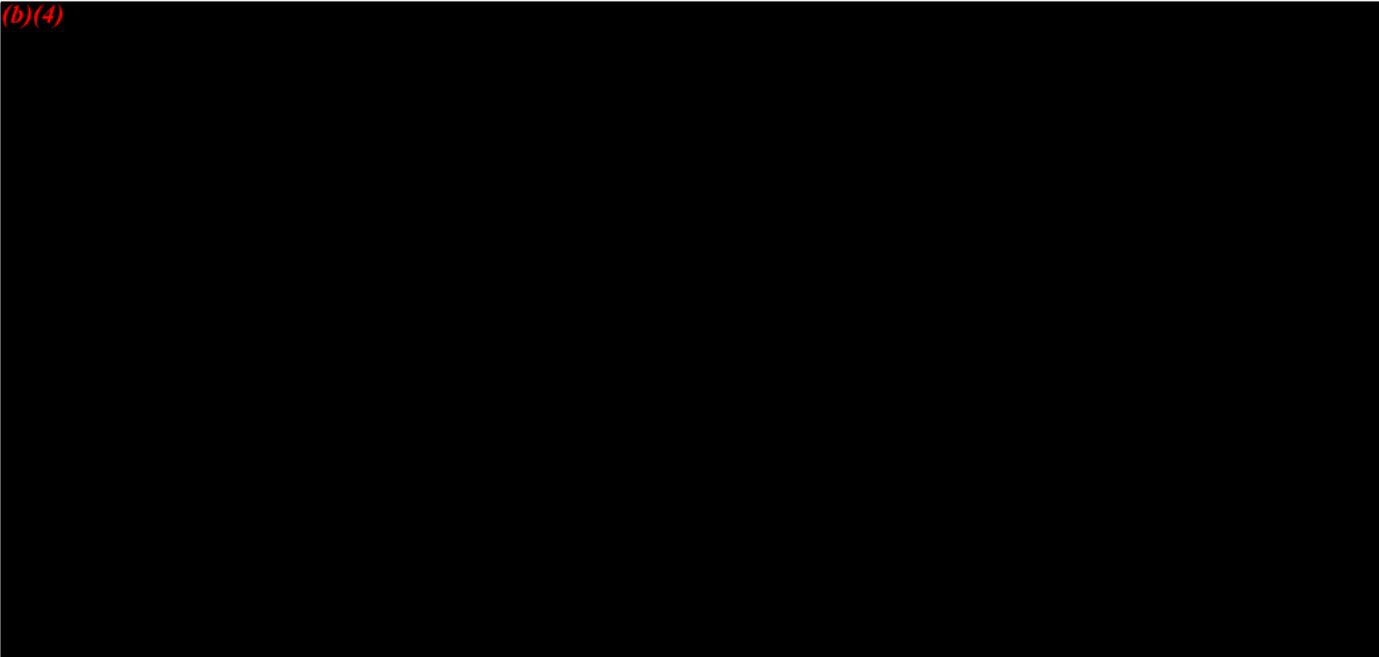
6. **Photographs or 3-D Drawings:** Photographs for the device are included in appendix 5.
7. **Engineering Drawings:** Engineering drawings, with dimensions and tolerances, are included in Appendix 6.
8. **Class III Summary:** Not applicable. This is a Class II device.
9. **Performance Data:**
 - a. **Bench Data:**

In accordance with ASTM F 623-99
 - b. **Comparative Claims:** No comparative claims are made for the VitalCare Urethral Catheter Red Rubber. It will not be compared in labeling or advertising to other.
 - c. **Unique Designs:** The design of the VitalCare Urethral Catheter Red Rubber is not unique.
 - d. **Biocompatibility Data:**

In accordance with ISO 10993
 - e. **Drug/Device compatibility:** The VitalCare Urethral Catheter Red Rubber is designed to facilitate the flow of urine from the bladder. Data demonstrating the compatibility of the catheter materials for this function is well established.
 - f. **Drug Stability:** Not applicable to this device.

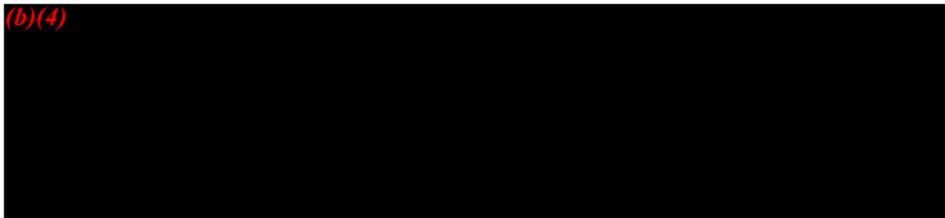
10. **Sterilization Information**

(b)(4)



g. **Contract Sterilizer Information:**

(b)(4)

A large black rectangular redaction box covers the majority of the page content under section g. The text "(b)(4)" is written in red at the top left corner of this redacted area.

11. **Kit Certification Statement:** N/A

12. **Guidance Document Issues:** This Premarket notification was prepared with reference to guidance document "Guidance For the Content of Premarket Notifications for Conventional and Anti-Microbial Urethral Catheter". Labeling was developed in accordance with FDA Device Labeling Guidance, Memorandum, G91-1.

Part I. Description of the Kendall Urethral Catheter Red Rubber (marketed Equivalent Device)

1. **Device Trade or Proprietary Name:**

Kendall Dover Red Rubber Robinson Catheter

2. **Device Common and Classification Name(s):**

Common Name: Urethral Catheter Red Rubber

Classification Name: Catheter, Urethral

3. **Classification Information:**

Class: Class II

Panel: Gastroenterology

Product Code: GBM

Cite: 21 CFR 876.5130

4. **Document Control Number**

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5. Description of the Marketed Equivalent Device

a. Type of Device: The Kendall Dover Red Rubber Robinson Catheter is a single use, flexible catheter. The proximal end of the catheter contains two opposing fenestrations designed to facilitate drainage from the bladder, the catheter is designed to facilitate attachment of the Urethral Catheter Red Rubber to an external urinary collection system to maintain a closed system.

b. Use with other devices.

Kendall Dover Red Rubber Robinson Catheter are to be used with urine collection devices and accessories.

c. Physical Specifications.

i. Components and materials.

Components are substantially equivalent to VitalCare components.

ii. Power Requirements: N/A

iii. Nominal dimensions:

8F- 22F X 398mm long nominal

d. Mechanical Specifications: N/A

e. Biological Specifications: N/A

f. Chemical Specifications

g. Compatibility requirements: N/A

6. Intended Use of the Marketed Equivalent Device:

To be inserted through the urethra to the bladder and utilized for the passage of fluid from the urinary tract.

7. Labels and Labeling:

Kendall Dover Red Rubber Robinson Catheter labeling is in Appendix 7

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APPENDIX I

Product Description

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VitalCare Product Description

Red Rubber Urethral Catheter:

The Urethral catheters are Red Rubber The Urethral catheters are to be used in the Nursing Home, Home Healthcare, and / or hospital environment to direct urine with incontinent patients and / or patients that are bedridden. The Urethral catheters are inserted through the Male / Female Urinary Track in to the Bladder.

Each of the Urethral catheters will be packed in a blister pack that is peel down type of packing. One Hundred (100) each of the single pouched Urethral catheters are packed in to a case box. Lot numbers and product date are stamped directly on the pouch, and will also be printed on the case labels.

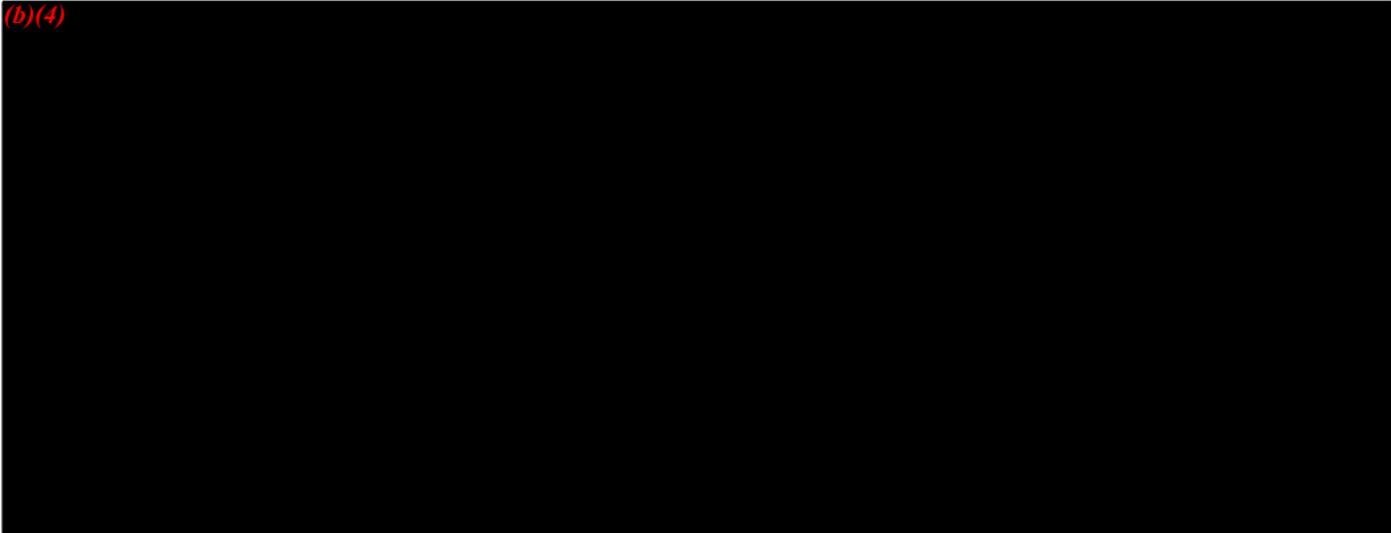
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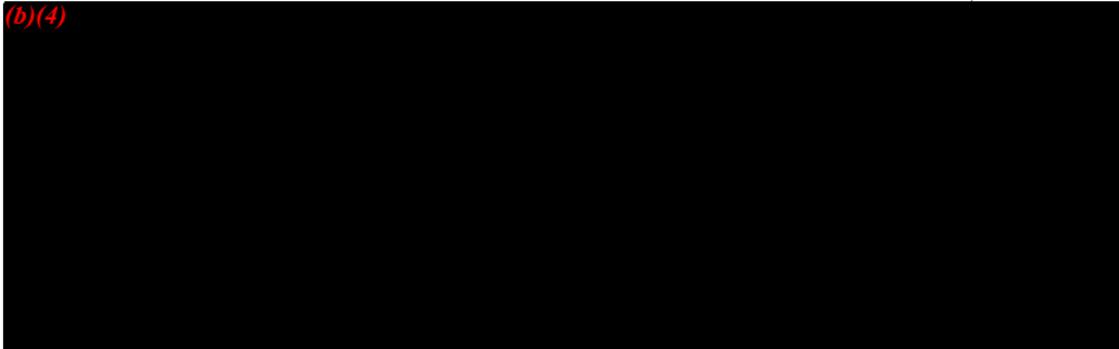
Urethral Red Rubber Pack Specification

(b)(4)



Label Specification

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APPENDIX II

Qualification Test Plan

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APPENDIX III

Sterile Pack / Box

100

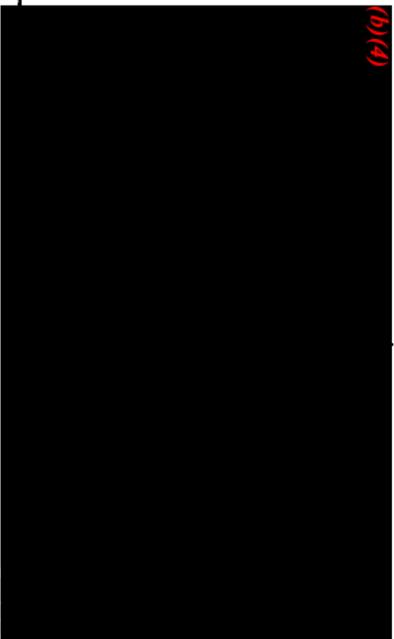
VITALCARE URETHRAL CATHETER Red Rubber

Contents:

② Single Use Only

100 pcs/case

Reorder No.:
Fr/Ch :
Lot No. :
Man. Date :
Exp. Date :



R-9881r0

VitalCare Carton Artwork (FRONT) prints 1 color. PMS 286 (blue) Size: 9.528" (24.2 cm) X 6.614" (16.8 cm)

ORIGINAL

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B-398120 Urethral Cath Catheter 3/11/02 4:51 PM Page 1

VITALCARE URETHRAL CATHETER Red Rubber

Contents:

② Single Use Only

100 pcs/case

(b)(4)

Reorder No.:
Fr/Ch :
Lot No. :
Man. Date :
Exp. Date :

VitalCare Miami, Florida 1-800-392-4547
(b)(4)

F-998110

VitalCare Caron Anwick (SIDE) prims 1 color, PMS 286 (blue) Size: 20.472" (52 cm) X 6.614" (16.8 cm)

Reduced at 80%

ORIGINAL

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APPENDIX IV

Instruction for Use

105

APPENDIX V

Photographs

107

APPENDIX VI

Drawings

111

APPENDIX VII

Kendall Labels

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tycra / Healthcare
KENDALL
DOVER
Reel Rubber Johnson Catheter

Reel Rubber Johnson Catheter
Catheter Johnson de Borracha Vermelho
Catheter Johnson de Borracha Vermelho
Catheter Johnson de Borracha Vermelho

CAUTION: This product contains natural rubber latex which may cause allergic reactions. **WARNING:** Do not use this device during pregnancy or while breastfeeding. **STERILE EO**
This product contains natural rubber latex which may cause allergic reactions. **WARNING:** Do not use this device during pregnancy or while breastfeeding. **STERILE EO**
This product contains natural rubber latex which may cause allergic reactions. **WARNING:** Do not use this device during pregnancy or while breastfeeding. **STERILE EO**

STERILE EO
Rx
2

Size: Tube - 50cm - Disposable
14FF
LOT No 1242012
888-660143
091008887600 430

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) May Ed Brown Knicker

Subject: 510(k) Number 1C 023872/S1

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

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

De Novo Classification Candidate? YES NO NA

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

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

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

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

The required certification and summary for class III devices NA

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

Animal Tissue Source YES NO

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

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

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

E2D
II, 876.5130, GBM, 78

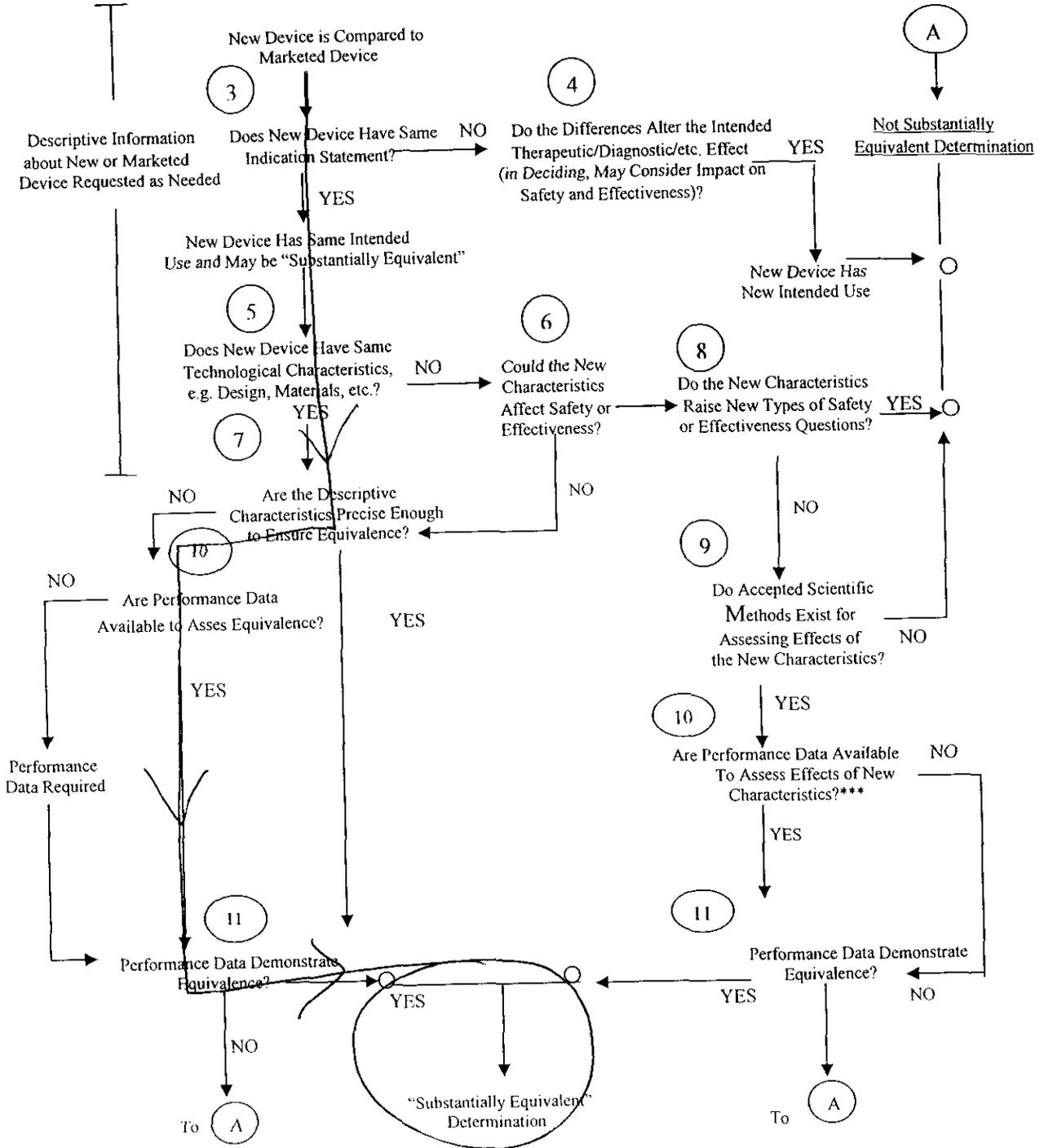
Review: V. Leo Nimmaladda ULDB April 03, 2003
(Branch Chief) for Janine Morris (Branch Code) (Date)

Final Review: E. Michael G. Segerson 4/9
(Division Director) (Date)

Revised: 8/17/99

4

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



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

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8/14
(b)(4)

Final Report

Mr. Michael McAvenia
VitalCare Group, Inc.
8935 NW 27th Street
Miami, FL 33172

Phone #: 305-620-4007
Fax #: 305-620-5220

MEM Elution Using L-929 Mouse Fibroblast Cells USP (Cytotoxicity)

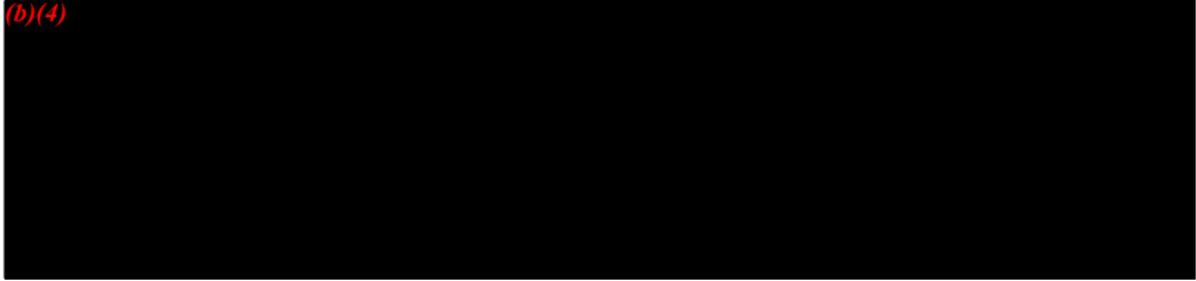
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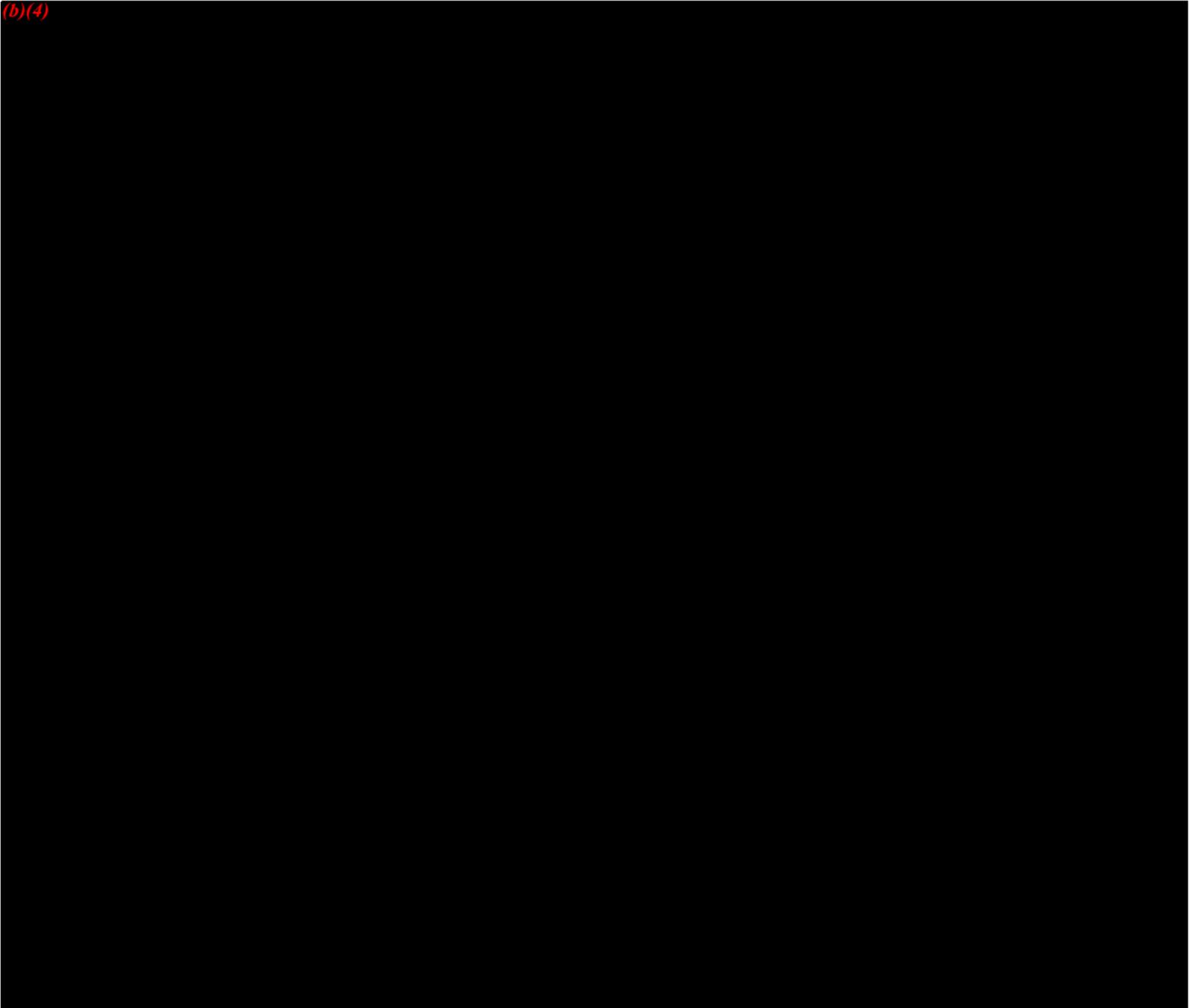


Test Report

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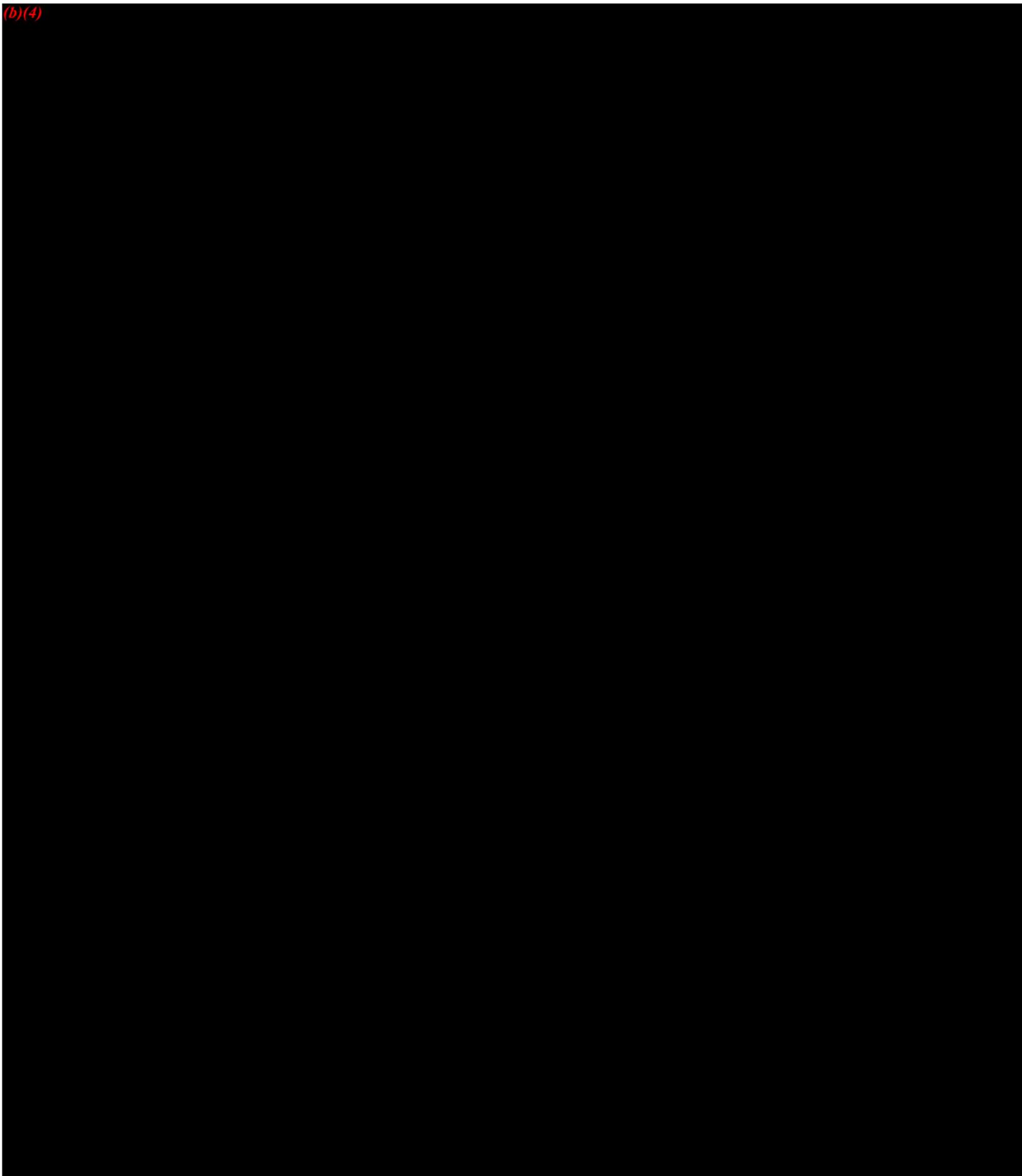
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Test Report

(b)(4)



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(b)(4)

Test Report

Skin Irritation Test

(b)(4)

(b)(4)

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| Conclusion..... | 4 |
| Record Storage..... | 4 |
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| Table 2 Dermal Observation..... | 5 |

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Mary Ed Bruce R. Dean

Subject: 510(k) Number K023872

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

- Refused to accept.
- Requires additional information (other than refuse to accept). *phone hold*
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate? YES NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Animal Tissue Source YES NO

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

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

Predicate Product Code with class:

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

Review: [Signature]
(Branch Chief)

ULDB
(Branch Code)

3/4/03
(Date)

Final Review: _____
(Division Director)

(Date)

Revised: 8/17/99

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

510(k) Number: K023872

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

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

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

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

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

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

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

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

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

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

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

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

Passed Screening Yes No
 Reviewer: Mary Obrien Kudman
 Concurrence by Review Branch: _____

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Date:

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

Q1

Internal Administrative Form

| | YES | NO |
|---|-----|-----|
| 1. Did the firm request expedited review? | | ✓ |
| 2. Did we grant expedited review? | | N/A |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | | ✓ |
| 4. If, not, has POS been notified? | | N/A |
| 5. Is the product a device? | ✓ | |
| 6. Is the device exempt from 510(k) by regulation or policy? | | ✓ |
| 7. Is the device subject to review by CDRH? | ✓ | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | ✓ |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | | N/A |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ |
| 11. If, yes, consult the ODE Integrity Officer. | | N/A |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991. | | N/A |

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K 023872/S 3

VI+ALCARE

February 25, 2003

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

Attention: Mary Beth O'Brien

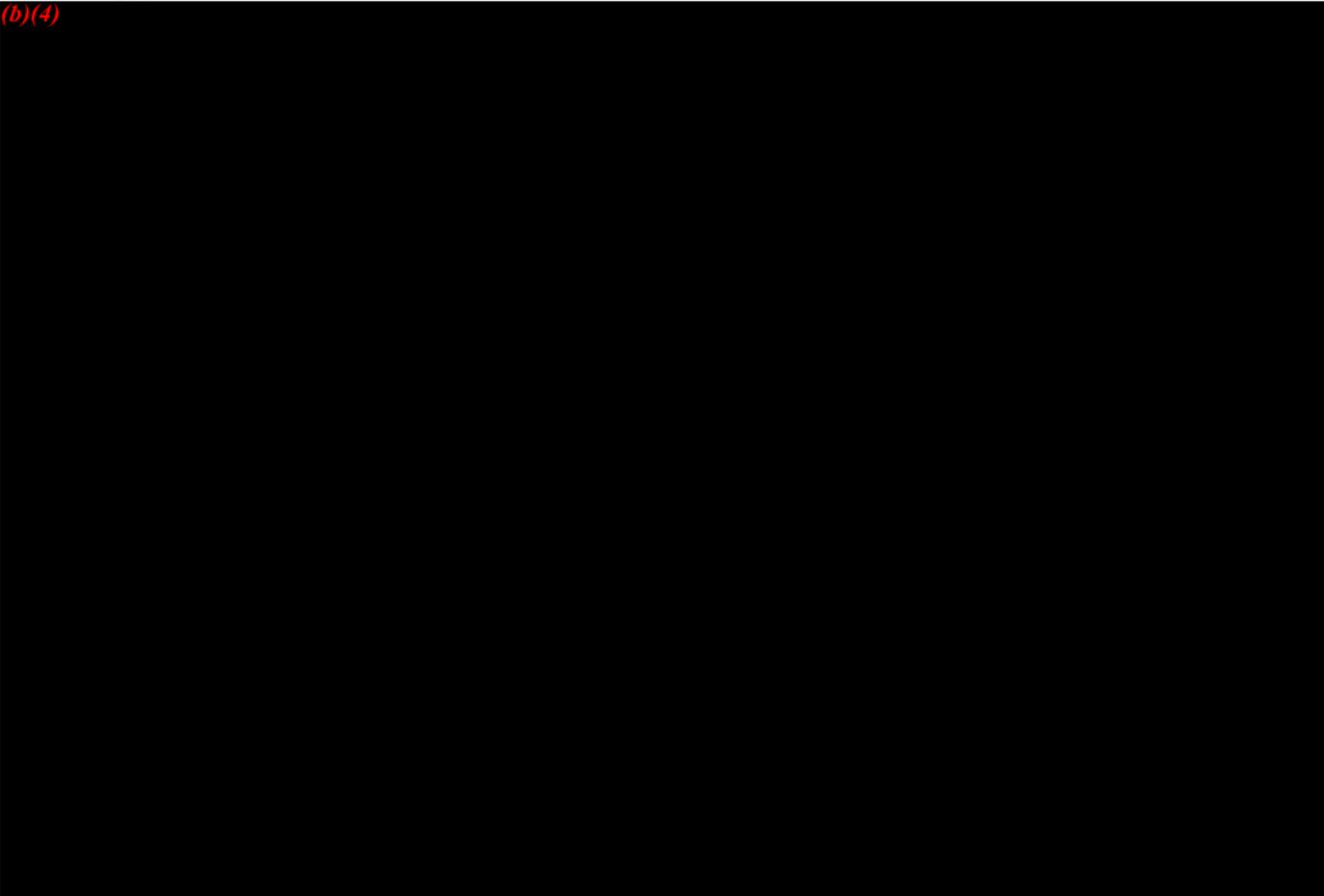
510(k) Numbers: K021938 Urethral Catheter, K021939 Foley Catheter and K023872 Red Rubber Catheter

Dear Mary Beth,

I have enclosed the additional information as requested for the above mentioned submissions. This information includes as follows:

FDA/OE DIVISION
2003 FEB 27
10:30

(b)(4)



Handwritten initials or signature at the bottom right of the redacted area.

(b)(4)



If you have any questions please contact me

A handwritten signature in black ink, appearing to read 'Michael McAvenia', is written over a horizontal line.

Michael McAvenia
Director Quality Assurance
Vitalcare Group Inc.

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