JAN 2 7 2003

K023254
Page 1 of 4

SpeediCath
510(k) SUMMARY
Page 1 of 4

1. **Submitter:**

Coloplast Corp
1940 Commerce Drive
Mankato, MN 56003
USA

Contact Person: Elizabeth Boots

Phone number: 507-386-4362

Fax number: 507-345-3291

Date of Preparation: September 19, 2002

2. **Device name:**

Classification Name: Urological Catheter
Common/usual name: Urinary Catheter for intermittent use
Proprietary Name: Speedicath

3. **Device Classification:**

The SpeediCath Catheter has been classified by the FDA under the heading of Urological Catheters and accessories as a Class II device.

4. **Statement of Substantial Equivalence:**

SpeediCath is substantially equivalent to the following predicate devices:

- EasiCath Set K973070, Coloplast Corp. Branded as the SureCath Set in the US.
- LoFric®Single Use Urinary Catheter K896750, Astra Tech Inc.
- LoFric®Plus Single Use Urinary Catheter K012374, Astra Tech Inc.

5. **Intended Use:**

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

6. **Device Description:**

The SpeediCath Catheter is a single use, disposable polyurethane catheter. It is coated and placed in a saline solution, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

K023254
Page 2 of 4

SpeediCath
510(k) SUMMARY
Page 2 of 4

Substantial equivalence comparison

A comparison matrix for the SpeediCath versus the predicate devices is presented below:

	SpeediCath	**EasiCath Set (identical to the SureCath Set) Coloplast Corp**	**LoFric®Single Use Urinary Catheter, Astra Tech Inc.**	**LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.**
510 (k) number		K973070	K896750	K012374
Device composition	Polyurethane catheter coated with polyvinylpyrrolidone, placed in a saline solution containing polyvinylpyrrolidone.	Polyvinylchloride catheter coated with polyvinylpyrrolidone, packed with an ampoule with sterile saline solution and sealed in a urine collection bag.	Polyvinylchloride catheter coated with polyvinylpyrrolidone and salt.	Polyether block amide catheter coated with polyvinylpyrrolidone and salt.
Sizes	Female Ch. 6, 8, 10, 12, 14, 16 Male Ch. 8, 10, 12, 14, 16, 18 Tiemann Ch. 10, 12, 14 Pediatric Ch. 6, 8,10 Boy Ch. 6, 8, 10, 12	Female Ch. 8, 10, 12, 14 Male Ch. 8, 10, 12, 14, 16, 18 Pediatric Ch. 6, 8, 10	Female 150mm Ch. 8, 10, 12, 14 Female 200mm Ch. 8, 10, 12, 14, 16, 18 Male Ch. 8, 10, 12, 14, 16, 18, 20, 22, 24 Tiemann Ch. 10, 12, 14, 16, 18 Pediatric 200mm Ch. 6, 8, 10 Boy Ch. 6, 8, 10 (Sizes currently on the market in the US)	Information not available

K023254
Page 3 of 4

SpeediCath
510(k) SUMMARY
Page 3 of 4

	SpeediCath	EasiCath Set (identical to the SureCath Set) Coloplast Corp	LoFric®Single Use Urinary Catheter, Astra Tech Inc.	LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.
Function of the device	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.
Indication for use	Chronic urine retention. Post-void residual volume (PVR). Voiding dysfunctions.	Chronic urine retention. Voiding dysfunctions.	Intended use is substantially equivalent to LoFric® Plus Single Use Urinary Catheter (according to K012374 Summary).	Intermittent catherization of the urethra.
Features of the device	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between the catheter and urethral mucosa.
Sterility	Sterile	Sterile	Sterile	Sterile
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack

K023254
Page 4 of 4

SpeediCath
510(k) SUMMARY
Page 4 of 4

7. Summary of Safety Testing:
A summary of the safety testing performed on the coated catheter is listed below.

Test	Reference	Results
Intracutaneous Test in the Rabbit	Scantox, DK Lab no.46511	"Negligible" according to ISO 10993, Part 10, Section 5.4.
Systemic Injection Test in the Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity, meeting the requirements of USP 24 (2000).
Vaginal Irritation Test – ISO Method	Sterilization Technical Services, USA Test no. T02-1551	Meets the requirements of Vaginal Irritation Test ISO Method (ISO 10993-10:1995).
Test for Delayed Contact Hypersensitivity Using the Guinea Pig Maximization Test	Scantox, DK Lab no. 46510	No evidence of delayed contact hypersensitivity according to ISO 10993, Part 10.
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK 46508	Passed the requirements of USP 24 (cytotoxicity grade ≤2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements of USP 25 (cytotoxicity grade ≤2)
Ames test	Scantox, DK Lab no. 48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonised Guidelines (1995 and 1997))

Conclusion: Passed all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2003

Ms. Elizabeth Boots
Vice President Quality Assurance
Coloplast Corp.
1940 Commerce Drive
NORTH MANKATO, MN 56003

Re: K023254
Trade/Device Name: SpeediCath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 GBM
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. Boots:

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.

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

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

Enclosure

K023254
Page 1 of 1

510(k) Number (if known): K023254

Device Name: SpeediCath

Indications for Use:

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Ragsdale

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023254

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2003

Ms. Elizabeth Boots
Vice President Quality Assurance
Coloplast Corp.
1940 Commerce Drive
NORTH MANKATO, MN 56003

Re: K023254
Trade/Device Name: SpeediCath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 GBM
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. Boots:

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.

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876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
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Other	(301) 594-4692

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Sincerely yours,

Nancy C. Brogdon

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

Enclosure

K023254

510(k) Number (if known): K023254

Device Name: SpeediCath

Indications for Use:

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023254

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 23, 2002

COLOPLAST CORP.
1940 COMMERCE DR.
NORTH MANKATO, MN 56003
ATTN: ELIZABETH BOOTS

510(k) Number: K023254
Product: SPEEDICATH

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

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

October 01, 2002

COLOPLAST CORP.
1940 COMMERCE DR.
NORTH MANKATO, MN 56003
ATTN: ELIZABETH BOOTS

510(k) Number: K023254
Received: 30-SEP-2002
Product: SPEEDICATH

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

K023254

Coloplast Corp.
1940 Commerce Drive
N. Mankato, MN 56002-8300

Telephone (507) 345-6200
Fax (507) 345-3291

Coloplast

September 5, 2002

RECEIVED
2002 SEP 30 P 1:49
FDA/CDRH/ODE/PMO

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

To Whom It May Concern:

I am sending two copies in temporary binders of a 510(k) submission for SpeediCath.

I may be reached at my direct dial line of 507-386-4362 or through the switchboard at 507-345-6200 for any comments or questions.

Sincerely,

Elizabeth Boots

Elizabeth Boots
Vice President Quality Assurance
Coloplast Corp
US Agent and Official Correspondent
Coloplast A/S

SCL p 10
For cover letter

GU
A
51435
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SpeediCath

510(k) Premarket Notification

September 19, 2002

RECEIVED
2002 SEP 30 P 1:55
CDRH/ODE/PMO

Coloplast Corp
1940 Commerce Drive
North Mankato, MN 56003
USA

SPEEDICATH
510(k) Premarket Notification

Applicant:
Elizabeth Boots
Quality Assurance Vice President
Coloplast Corp
1940 Commerce Drive
North Mankato, MN 56003
USA
Phone no.: 507-386-4362
Fax no.: 507-345-3291

Signature: Elizabeth Boots
Elizabeth Boots

Manufacturer:
Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark

Distributor:
Coloplast Corp
1955 West Oak Circle
Marietta, GA 30062-2249
USA

Sterilization facility:
(b)(4) Third Party Information

Table of Contents

SpeediCath Catheter
Coloplast Corp

Premarket Submission Cover sheets (4)

CDRH SUBMISSION COVER SHEET

Date of Submission: September 19, 2002 **FDA Document Number:**

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission Summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	Original Submission: ■ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated ☐ Report Amendment	☐ Pre-IDE mtg ☐ Pre-PMA m ☐ Pre-PDP mt ☐ 180-Day mt ☐ Other (speci

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submiss
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original Submission ☐ Additional Information	☐ Original Submission ☐ Additional Information	Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name: Coloplast Corp		Establishment registration number: 2125337	
Division Name (if applicable):		Phone number (include area code): 507-386-4362	
Street Address: 1940 Commerce Drive		Fax number (include area code): 507-345-3291	
City: North Mankato	State/Province: Minnesota	Zip code: 56003	Country: USA
Contact Name: Elizabeth Boots			
Contact Title: Quality Assurance Vice President		Contact e-mail address: mnbb@coloplast.com	

Section C — Submission Correspondent (if different from above)

Company/Institution Name:		Establishment registration number:	
Division name (if applicable)		Phone number (include area code):	
Street Address:		Fax number (include area code):	
City:	State/Province:	Zip Code:	Country
Contact Name:			

Section D1 **Reason for Submission – PMA,PDP, or HDE**

☐ New Device
☐ Withdrawal
☐ Additional or Expanded Indications
☐ Licensing Agreement

☐ Change in design, component, or specification:
- ☐ Software
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other (specify below)

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager
- ☐ Distributor

☐ Processing Change:
- ☐ Manufacturing
- ☐ Sterilization
- ☐ Packaging
- ☐ Other (specify below)

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other (specify below)_

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post Approval Study
- ☐ Adverse Reaction
- ☐ Device Defect
- ☐ Amendment

☐ Response to FDA correspondence:
- ☐ Request for applicant hold
- ☐ Request for removal of applicant hold
- ☐ Request for extension
- ☐ Request to remove or add manufacturing site

☐ Change in Ownership
☐ Change in correspondent

☐ Other Reason (specify):

Section D2 **Reason for Submission - IDE**

☐ New device
☐ Addition of institution
☐ Expansion/extension of study
☐ IRB certification
☐ Request hearing
☐ Request waiver
☐ Termination of study
☐ Withdrawal of application
☐ Unanticipated adverse effect
☐ Notification of emergency use
☐ Compassionate use request
☐ Treatment IDE
☐ Continuing availability request

Change in:
- ☐ Correspondent
- ☐ Design
- ☐ Informed consent
- ☐ Manufacturer
- ☐ Manufacturing process
- ☐ Protocol – feasibility
- ☐ Protocol – other
- ☐ Sponsor

☐ Report Submission:
- ☐ Current investigator
- ☐ Annual progress
- ☐ Site waiver limit reached
- ☐ Final

☐ Response to FDA letter concerning:
- ☐ Conditional approval
- ☐ Deemed approval
- ☐ Deficient final report
- ☐ Deficient progress report
- ☐ Deficient investigator report
- ☐ Disapproval
- ☐ Request extension for time to respond to FDA
- ☐ Request meeting

☐ Other reason (specify):

Section D3 **Reason for Submission – 510(k)**

■ New Device
☐ Additional or expanded indications
☐ Other reason (specify):

☐ Change in technology
☐ Change in design

☐ Change in materials
☐ Change in manufacturing process

Section E **Additional Information on 510(k) Submissions**

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning safety effectiveness data: ■ 510(k) summary attached ☐ 510(k) statement
1EZD	2 KOD	3 GBM	4	
5	6	7	8	

510(k) Number	Trade of Proprietary or model name	Manufacturer
1 K973070	1 Conveen EasiCath Set	1 Coloplast A/S
2 K896750	2 LoFric®Single Use Urinary Catheter	2 Astra Tech Inc.
3 K012374	3 LoFric®Plus Single Use Urinary Catheter	3 Astra Tech Inc.
4	4	4
5	5	5
6	6	6

Section F ***Product Information – Applicable to All Applications***

Common or usual name or classification name: Urinary Catheter for intermittent use

Trade or proprietary or model name	Model Number
1 SpeediCath	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ■ Laboratory Testing ■ Animal Trials ☐ Human Trials

Section G **Product Classification – Applicable to All Applicants**

Product code: GBM	C.F.R. Section: 876.5130	Device Class:
Classification Panel: Gastroenterology and Urology		☐ Class I ■ Class II ☐ Class III ☐ Unclassified

Indications (from labeling): "The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain."

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

■ Original ☐ Add ☐ Delete	FDA establishment registration number:	■ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler
Company/Institution name: Coloplast A/S		Establishment registration number: 9610694
Division name (if applicable):		Phone number (include area code): +45 4911 1111
Street address: Holtedam 1		FAX number (include area code): +45 4911 1249
City: Humlebaek	State/Province	Zip code: DK-3050 / Country: Denmark
Contact name: Mogens Svanum		
Contact title: Quality Assurance Manager		

■ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ■ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/relabeler

(b)(4) Third Party Information

[redacted]

☐ Original ☐ Add ☐ Delete	FDA Establishment registration number:	☐ Manufacturer ☐ Contract sterilizer ☐ Contract Manufacturer ☐ Repackager/relabel

Company/Institution name:	Establishment registration number:		
Division name (if applicable):	Phone number (include area code):		
Street address:	FAX number (include area code):		
City:	State/Province:	Zip code:	Country:
Contact name:			
Contact title:	Contact e-mail address:		

SE

Transmittal Letter

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

Attention: Document Control Clerk

RE: 510(k) Premarket Notification

RECEIVED
2002 SEP 30 P 1:55
FDA/CDRH/OSE/PMO

Coloplast Corp, in accordance with the requirements of Section 510(k) of the Food, Drug, and Cosmetic Act, is requesting permission to manufacture and market the SpeediCath Catheter.

Coloplast Corp requests that the Food and Drug Administration hold as confidential information our intent to market the SpeediCath Catheter.

We consider our intent to market this device to be confidential commercial information and, therefore, exempt from public disclosure. To the best of my knowledge, neither I nor anyone else has disclosed through advertising, or any other manner, our intent to market this device to scientists, market analysts, exporters, or other individuals except employees of, paid consultants to, our company or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy.

We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 311 (q).

It is our intent to begin marketing this device as soon as the FDA finds it to be substantially equivalent to other devices already on the market.

If you have any questions or require additional information, please do not hesitate to call.

Sincerely, Elizabeth Boots

Elizabeth Boots
Quality Assurance Vice President
Coloplast Corp
1940 Commerce Drive
North Mankato, MN 56003
USA
Phone no.: 507-386-4362
Fax no.: 507-345-3291

Indications For Use

510(k) Number (if known):_____

Device Name: SpeediCath

Indications for Use:

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

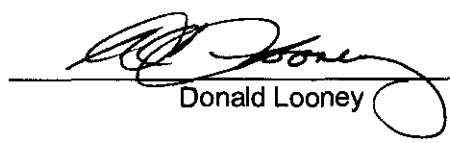
Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87(*k*))

I certify that, in my capacity as President of Coloplast Corp, 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 has been omitted.



Donald Looney

29 AUG 2002

Date

Premarket Notification (510(k)) Number

56

SECTION 1: General Information

Classification Name: Urological catheter (and accessories)
Classification Number: GBM
Classification Panel: Gastroenterology and Urology
C.F.R. Section: 876.5130
Common/Usual Name: Urinary Catheter for intermittent use
Proprietary Name: SpeediCath

Applicant Name and address:

Coloplast Corp
1940 Commerce Drive
North Mankato, MN 56003
USA

Establishment Registration No.: 2125337

Distributor Name and address:

Coloplast Corp
1955 West Oak Circle
Marietta, GA 30062-2249
USA

Establishment Registration No.: 1046831

Manufacturer Name and Address:

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark

Establishment Registration No.: 9610694

Address of Sterilization Facility:

(b)(4) Third Party Information

Establishment Registration No.: (b) (4) (4)n d

Contact person:

Elizabeth Boots
Quality Assurance Vice President
Coloplast Corp
1940 Commerce Drive
North Mankato, MN 56003
USA
Phone no.: 507-386-4362
Fax no.: 507-345-3291

Product Classification Number:	Class II Device
Reason for the Premarket Notification:	New Device
Performance Standards:	Not applicable

SECTION 2: 510(k) Summary

A 510(k) summary conforming to the content and format requirements specified in 21 CFR §807.92 is provided on the following pages:

LeO

SpeediCath
510(k) SUMMARY
Page 1 of 4

1. **Submitter:**

Coloplast Corp
1940 Commerce Drive
Mankato, MN 56003
USA

Contact Person: Elizabeth Boots

Phone number: 507-386-4362

Fax number: 507-345-3291

Date of Preparation: September 19, 2002

2. **Device name:**

Classification Name: Urological Catheter
Common/usual name: Urinary Catheter for intermittent use
Proprietary Name: Speedicath

3. **Device Classification:**

The SpeediCath Catheter has been classified by the FDA under the heading of Urological Catheters and accessories as a Class II device.

4. **Statement of Substantial Equivalence:**

SpeediCath is substantially equivalent to the following predicate devices:

- EasiCath Set K973070, Coloplast Corp. Branded as the SureCath Set in the US.
- LoFric®Single Use Urinary Catheter K896750, Astra Tech Inc.
- LoFric®Plus Single Use Urinary Catheter K012374, Astra Tech Inc.

5. **Intended Use:**

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

6. **Device Description:**

The SpeediCath Catheter is a single use, disposable polyurethane catheter. It is coated and placed in a saline solution, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

lcl

SpeediCath
510(k) SUMMARY
Page 2 of 4

Substantial equivalence comparison

A comparison matrix for the SpeediCath versus the predicate devices is presented below:

	SpeediCath	**EasiCath Set (identical to the SureCath Set) Coloplast Corp**	**LoFric®Single Use Urinary Catheter, Astra Tech Inc.**	**LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.**
510 (k) number		K973070	K896750	K012374
Device composition	Polyurethane catheter coated with polyvinylpyrrolidone, placed in a saline solution containing polyvinylpyrrolidone.	Polyvinylchloride catheter coated with polyvinylpyrrolidone, packed with an ampoule with sterile saline solution and sealed in a urine collection bag.	Polyvinylchloride catheter coated with polyvinylpyrrolidone and salt.	Polyether block amide catheter coated with polyvinylpyrrolidone and salt.
Sizes	Female Ch. 6, 8, 10, 12, 14, 16 Male Ch. 8, 10, 12, 14, 16, 18 Tiemann Ch. 10, 12, 14 Pediatric Ch. 6, 8,10 Boy Ch. 6, 8, 10, 12	Female Ch. 8, 10, 12, 14 Male Ch. 8, 10, 12, 14, 16, 18 Pediatric Ch. 6, 8, 10	Female 150mm Ch. 8, 10, 12, 14 Female 200mm Ch. 8, 10, 12, 14, 16, 18 Male Ch. 8, 10, 12, 14, 16, 18, 20, 22, 24 Tiemann Ch. 10, 12, 14, 16, 18 Pediatric 200mm Ch. 6, 8, 10 Boy Ch. 6, 8, 10 (Sizes currently on the market in the US)	Information not available

SpeediCath
510(k) SUMMARY
Page 3 of 4

	SpeediCath	EasiCath Set (identical to the SureCath Set) Coloplast Corp	LoFric®Single Use Urinary Catheter, Astra Tech Inc.	LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.
Function of the device	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.
Indication for use	Chronic urine retention. Post-void residual volume (PVR). Voiding dysfunctions.	Chronic urine retention. Voiding dysfunctions.	Intended use is substantially equivalent to LoFric® Plus Single Use Urinary Catheter (according to K012374 Summary).	Intermittent catherization of the urethra.
Features of the device	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between the catheter and urethral mucosa.
Sterility	Sterile	Sterile	Sterile	Sterile
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack

SpeediCath
510(k) SUMMARY
Page 4 of 4

7. Summary of Safety Testing:
A summary of the safety testing performed on the coated catheter is listed below.

Test	Reference	Results
Intracutaneous Test in the Rabbit	Scantox, DK Lab no.46511	"Negligible" according to ISO 10993, Part 10, Section 5.4.
Systemic Injection Test in the Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity, meeting the requirements of USP 24 (2000).
Vaginal Irritation Test – ISO Method	Sterilization Technical Services, USA Test no. T02-1551	Meets the requirements of Vaginal Irritation Test ISO Method (ISO 10993-10:1995).
Test for Delayed Contact Hypersensitivity Using the Guinea Pig Maximization Test	Scantox, DK Lab no. 46510	No evidence of delayed contact hypersensitivity according to ISO 10993, Part 10.
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK 46508	Passed the requirements of USP 24 (cytotoxicity grade ≤2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements of USP 25 (cytotoxicity grade ≤2)
Ames test	Scantox, DK Lab no. 48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonised Guidelines (1995 and 1997))

Conclusion: Passed all tests.

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SECTION 3: Device Description:

Intended Use:

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

Device Description:

The SpeediCath catheter is a ready to use single use, disposable polyurethane catheter. It is hydrophilic coated and placed in a sterile filtered saline solution, packed and then sealed in a foil bag and sterilized.

To use, the user opens the foil bag, takes out the catheter and inserts it into the urethra.

The uncoated catheter is purchased as a raw material, which is then applied with a hydrophilic coating. It is only the coating that is in direct contact with the urethral mucosa.

The coating on the catheter consists of one layer and is composed of the following raw materials:

Polyvinylpyrrolidone (PVP)

(b)(4) [redacted]

Salt (NaCl)

(b)(4) [redacted]

(b)(4) [redacted]

CONFIDENTIAL

The saline solution in the foil bag (b)(4) (b)(4) . The saline solution also contains polyvinylpyrrolidone to maintain the (b)(4) (b)(4) The PVP ensures the low friction of the catheter.

(b)(4)

The catheter comes in a 200 mm length (Female and Pediatric), 300 mm length (Boy) and 400 mm length (Male and Tiemann).

CONFIDENTIAL

SpeediCath Descriptive Drawings:

Descriptive drawings for SpeediCath are provided on the following page.

(b)(4) – MATERIAL OUTLINE

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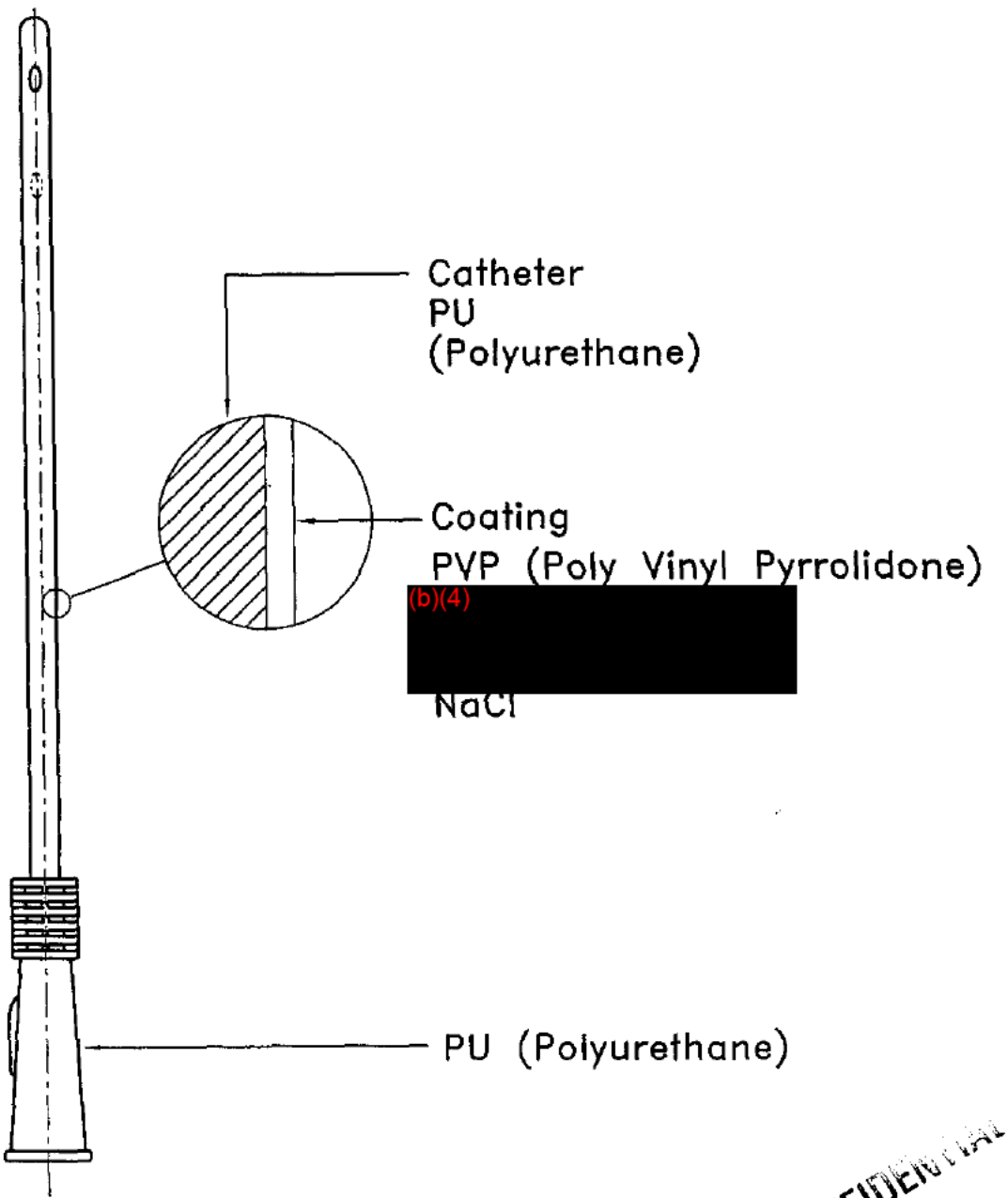
SpeediCath

July 2002

(b)(4)



CONFIDENTIAL

Packing :

(b)(4)

CONFIDENTIAL

Color additives:

All colors in SpeediCath conform to Parts 178.3297 Colorants for polymers, Food and Drugs Administration USA, 1:st of April 1995 regarding packaging materials, which may be used in contact with food. Coloplast Corp considers these colors safe for use in the SpeediCath Catheter.

The polyurethane catheter is colored light blue with the color (b)(4) [redacted]. Polyurethane becomes yellow in the sterilization process, therefore the blue color in the catheter makes it appear light green after sterilization, thus appearing more aesthetic to the user.

The connector is colored in different colors according to size. This makes it easy for the end user to identify the correct size of the catheter. The colors appear from the table below. The connector is used to connect the catheter to a urine bag or otherwise as drainage tube for the urine. The connector is only in contact with skin on the hands/fingers when using the catheter. Thus the connector allows the user to handle the catheter without touching and thereby contaminating the tube before insertion into the urethral mucosa.

Size	Color
Ch 6	Green, (b)(4) [redacted]
Ch 8	Blue, (b)(4) [redacted]
Ch 10	Black, (b)(4) [redacted]
Ch 12	White, (b)(4) [redacted]
Ch 14	Green, (b)(4) [redacted]
Ch 16	Orange, ([redacted]
Ch 18	Red, (b)(4) [redacted]

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(b)(4) Third Party Certification

(b)(4) Third Party Certification

(b)(4) Third Party Certification

(b)(4) Third Party Certification

(b)(4) Third Party Certification

(b)(4) Third Party Certification

(b)(4) Third Party Certification

SECTION 4: Comparative Information

For the purpose of submitting premarket notification in accordance with Section 5.10 (k) of the Federal Food, Drug and Cosmetic Act, Coloplast Corp considers Speedi-Cath to be substantially equivalent to the predicate devices:

EasiCath Set, Coloplast Corp, K973070
LoFric®Single Use Urinary Catheter, Astra Tech, Inc., K896750
LoFric® Plus Single Use Urinary Catheter, Astra Tech, Inc., K012374.

The intended use of these products is the same. Substantial equivalence is evident from the tabular comparison starting on next page and the discussion below:

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE (1/3)

	SpeediCath	EasiCath Set (identical to the SureCath Set)	LoFric® Single Use Urinary Catheter	LoFric® Plus Single Use Urinary Catheter
Manufacturer	Coloplast Corp	Coloplast Corp	Astra Tech Inc.	Astra Tech Inc.
510(k) number		K973070	K896750	K012374
Device class	Class II	Class II	Class II	Class II
Product code	GBM	EZD	KOD	GBM
Indications for use	The catheter is indicated for use by patients with chronic urine retention and patients with a post-void residual volume (PVR) *due to neurogenic and non-*neurogenic voiding dysfunctions.	The catheter is indicated for use by patients with chronic urine retention due to neurogenic and non-neurogenic voiding *dysfunctions.*	Intended use is substantially equivalent to LoFric® Plus Single Use Urinary Catheter (according to K012374 Summary)	The catheter is intended for intermittent catherization of the urethra.
Function of device	The catheter is inserted into the urethra to reach the bladder allowing urine to drain	The catheter is inserted into the urethra to reach the bladder allowing urine to drain into the attached urine bag.	The catheter is inserted into the urethra to reach the bladder allowing urine to drain	The catheter is inserted into the urethra to reach the bladder *allowing urine to drain*
Catheter composition	Polyurethane catheter	Polyvinylchloride catheter	Polyvinylchloride catheter	Polyether block amide (PEBA) catheter
Coating	Polyvinylpyrrolidone (and salt *(NaCl) that is absorbed from the* saline solution)	Polyvinylpyrrolidone	Polyvinylpyrrolidone (PVP) and *salt (NaCl)*	Polyvinylpyrrolidone (PVP) and *salt (NaCl)*
Hydrophilic coating	yes	yes	yes	yes
Low friction	yes	yes	yes	yes

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE (2/3)

	SpeediCath	EasiCath Set (identical to the SureCath Set)	LoFric® Single Use Urinary Catheter	LoFric® Plus Single Use Urinary Catheter
Sterile saline solution included in peel pack	yes	yes	no	no
Lubricating solution	The sterile saline solution contains polyvinylpyrrolidone (PVP) to avoid the PVP in the coating to be washed out. The saline solution activates the coating, creating a lubricating surface	The sterile saline solution is packed in an ampoule and placed in the urine bag. When the ampoule is broken the catheter coating gets activated creating a lubricating surface	The user adds water into the peel pack, creating a lubricating coating on the catheter	The user adds water into the peel pack, creating a lubricating coating on the catheter
Urine bag included in peel pack	no	yes	no	no
Duration of use	For intermittent use	For intermittent use	For intermittent use	For intermittent use
Sterility	Sterile	Sterile	Sterile	Sterile
Use (single, reusable, disposable)	Single use	Single use	Single use	Single use
Storage recommendations	To be kept dry and at room temperature. However exposure to extreme temperatures [below 0°C (32°F) and above 50°C (122°F)] for up to 24 hours will not damage the performance of the catheters.	To be kept dry at room temperature. However exposure to extreme temperatures [below -10°C (14°F) and above 40°C (104°F)] for max. 1 week will not damage the catheters.	Store in a dry place at room temperature. There should not be direct contact with sunlight. Temperature range should remain below 86°F. Keep away from high humidity environments.	Information not available

SUBSTANTIAL EQUIVALENCE COMPARISON TABLE (3/3)

	SpeediCath	EasiCath Set (identical to the SureCath Set)	LoFric® Single Use Urinary Catheter	LoFric® Plus Single Use Urinary Catheter
Sizes in the US	Female Ch. 6, 8, 10, 12, 14, 16 Male Ch. 8, 10, 12, 14, 16, 18 Tiemann Ch. 10, 12, 14 Pediatric Ch. 6, 8,10 Boy Ch. 6, 8, 10, 12	Female Ch. 8, 10, 12, 14 Male Ch. 8, 10, 12, 14, 16, 18 Pediatric Ch. 6, 8,.10	Female 150mm Ch. 8, 10, 12, 14 Female 200mm Ch. 8, 10, 12, 14, 16, 18 Male Ch. 8, 10, 12, 14, 16, 18, 20, 22, 24 Tiemann Ch. 10, 12, 14, 16, 18 Pediatric 200mm Ch. 6, 8, 10 Boy Ch. 6, 8, 10 (Currently on the market in the US)	Information not available
Lengths	Female and pediatric: 200mm (8inch) Male and tiemann: 400mm (16inch) Boy: 300mm (12inch)	Female and pediatric: 200mm (8inch) Male: 400mm (16inch)	Female and pediatric: 150mm (6inch) and 200mm (8inch) Male and tiemann: 400mm (16 inch) Boy: 300mm (12inch)	Information not available
Packaging	Peel pack	Peel pack	Peel pack	Peel pack
Prescription/OTC-use		Prescription use	Prescription use	Prescription use

Discussion of similarities and differences

Basically, the SpeediCath catheter and the predicate devices are substantially equivalent in intended use and are recommended for similar indications.

Other features that SpeediCath has in common with the predicate devices are that they are all sterile, single use intermittent catheters. Furthermore, they are all hydrophilic coated with polyvinylpyrrolidone and packed singularly in peel packs.

SpeediCath comes without the urine bag and the predicate devices, LoFric® Single Use Urinary Catheter and LoFric® Plus Single Use Urinary Catheter, are also available in packs without the urine bag.

The hydrophilic coatings on SpeediCath and the predicate devices provide lubricating and low-friction surfaces thereby reducing the risk of long-term damage to the urethral mucosa. All the coatings are made of polyvinylpyrrolidone, which is commonly used in medical devices in the US and is toxicological and clinically well documented for skin and mucosa contact.

Included in both the SpeediCath catheter and the predicate device, EasiCath Set, comes a sterile saline solution that ensures the safe clean water, needed to activate the coating. (b)(4) [redacted]. The intended use of the integrated water is the same and the products are therefore considered to be substantially equivalent with regard to the safety and effectiveness of the water. Having the solution integrated in each package makes the use of the catheter easy, fast and hygienic. SpeediCath is furthermore ready to use (no need to wait for the coating to get activated – always optimum hydration) and easy to open, thereby improving ease of use for patients.

Both the SpeediCath catheter and the predicate device LoFric® Plus Single Use Urinary Catheter are free of polyvinylchloride, a feature that makes them friendlier towards the environment. SpeediCath is made of polyurethane, which is commonly used in medical devices.

The SpeediCath packaging is made of foil with (b)(4) [redacted]. All layers of the packaging are made of materials that are commonly used to handle food. The foil keeps the saline solution from evaporating, thereby ensuring an optimum amount of saline solution in the packaging. The amount of foil used is approx. 1.5 and 2.7 grams for female and male packages, respectively. In comparison, the amount of foil used for a typical Danish lunch pack is approx. 3-4 grams.

As seen in the above tabular presentation and discussion SpeediCath does not raise any new questions about safety and effectiveness and Coloplast Corp considers SpeediCath to be substantially equivalent to the predicate devices.

SECTION 5: Substantially Equivalent Device Labeling

Copies of available labeling for the predicate devices mentioned below are enclosed on the following pages.

EasiCath Set K973070, Coloplast Corp. Branded as the SureCath Set in the US.

LoFric®Single Use Urinary Catheter K896750, Astra Tech Inc.

LoFric®Plus Single Use Urinary Catheter K012374, Astra Tech Inc. (Labeling not available).

SureCath Set

Address label:

Coloplast Corp.
1955 West Oak Circle
Marietta
Georgia 30062

Toll Free Telephone:
800/533-0464

Made in Denmark

06093 LOT 12378.45 2005-06

(01)00762123030691(17)050600(10)01237845

CE 0088

Retail label:

SureCath Set
28005

11701-899-05

Coated catheter
for single use
integrated in bag
Nelaton male/700 ml
20 units

STERILE EO

FR 8/2.7 mm

LOT 12342.12
2005-06
To be kept dry

7 621230306 9 1

Shipper label:

Coloplast Corp. - Georgia, US **06093**

No. 280050

SureCath Set
Coated catheter
for single use integrated in bag
Nelaton male/700 ml
FR 8/2.7 mm
11701-899-05
4 x 20 units

LOT **12345.12**

2005-06

CE 0088

7 621230307 0 7

(01)00762123030707(17)050600(10)01234512(93)5005

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Packaging:

SureCath Set

Coated catheter integrated in urine bag
For single use only. Sterile unless package is opened or damaged.

Sonde vésicale pré-lubrifiée avec poche de recueil
Vérifier l'intégrité du protecteur individuel de stérilité avant usage. A usage unique.

Sonda pre-lubricada con bolsa integrada
De un sólo uso. Producto estéril hasta que se abra o se dañe el envase.

CAUTION:
Federal (USA) law restricts this device to be sold only by or on order of a physician.

Distributed by:
Coloplast Corp.
Marietta, GA 30062-2249
(770) 281-8400

Manufactured by Coloplast A/S, DK-3050 Humlebæk, Denmark.
SureCath is a trade mark pending for registration by Coloplast A/S.
© All rights reserved Coloplast A/S, DK-3050 Humlebæk, Denmark.

Coloplast

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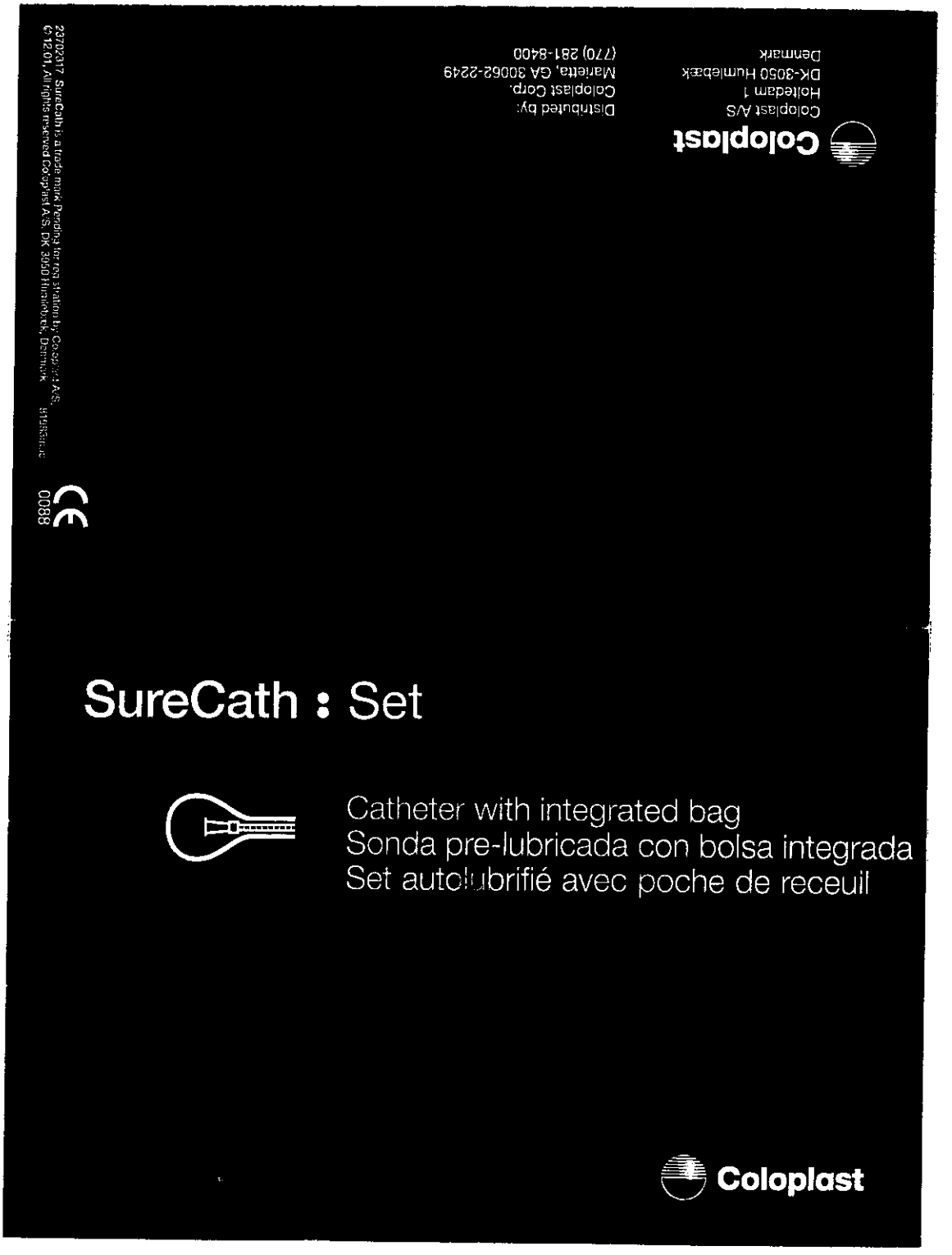
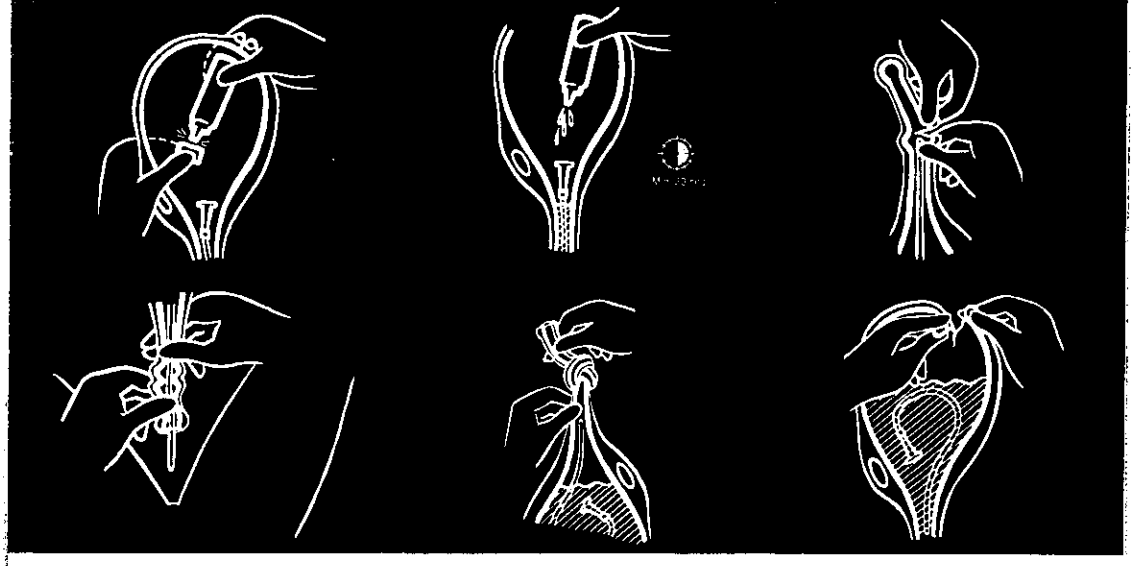

Coloplast
Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark
Distributed by:
Coloplast Corp.
Marietta, GA 30062-2249
(770) 281-8400
CE
0086
SureCath : Set
Catheter with integrated bag
Sonda pre-lubricada con bolsa integrada
Set autolubrifié avec poche de receuil
Coloplast

: Illustration



SureCath : Set

FR	STERILE EO	700 ml	700 ml	700 ml	700 ml	1200 ml
6					28011	
8		28005				
10		28006	28016			
12		28007	28017	28003		28027
14		28008	28018	28004		28028
16		28009	28019			

Not available in all countries

SureCath : Set with Accessories

FR	STERILE EO	700 ml	700 ml	1200 ml
14		28032	28034	28036
16		28033		28037

English

SureCath Integrated in Bag

1. Open the package and take out the bag. Break the ampule and squeeze out the water into the bag. Hold the bag with the catheter pointing downwards.

2. Wait for at least 30 seconds.

3. Turn the bag upside down and open it by tearing off the tip.

4. Insert the catheter into the urethra by gently pushing it out of the bag. When the urine stops flowing, ease out the catheter 2 to 3 cm. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1 to 2 cm. When the bladder is empty, slowly remove the catheter from the urethra while inserting it into the bag.

5. Make a knot at the end of the bag.

6. Throw the bag into an appropriate waste container or open it at the other end and empty it.

Single use only.

Do not reuse or re-sterilize product.

Coloplast accept no liability for any injury or other loss that may arise in the use of this product in a manner contrary to Coloplast's current recommendations.

Francais

SureCath avec Poche de Receuil

1) Enlever le papier protecteur et sortir le set. Casser l'extrémité de l'ampoule et presser pour vider l'eau dans la poche. Tenir la poche avec la sonde dirigée vers le bas.

2) Attendre au moins 30 secondes.

3) Retourner la poche et l'ouvrir en déchirant l'extrémité.

4) Introduire la sonde dans l'urètre en la sortant doucement de la poche. Quand l'urine s'arrête de couler, retirer la sonde de 2 ou 3 cm. Si l'urine coule à nouveau, attendre quelques secondes avant de la retirer de 1 ou 2 cm. Une fois la vessie vide, ressortir doucement la sonde de l'urètre tout en la rentrant dans la poche.

5) Nouer l'extrémité de la poche.

6) Jeter la poche dans une poubelle ou l'ouvrir par le bas et la vider.

A usage unique.

Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Ne pas restériliser.

Coloplast ne peut être tenu responsable des dommages pouvant résulter de l'emploi du produit dans des conditions non conformes aux instructions données dans la notice d'utilisation.

Español

SureCath con Bolsa Integrada

1. *Abra el envase y retire el Set del mismo. Desdoble la* bolsa. Sujete la bolsa con la punta de la sonda mirando hacia abajo. Abra la ampolla girando la pestaña de la misma, y presiónela hasta vaciar por completo su contenido.

2. Espere por lo menos 30 segundos.

3. Invierta la posición de la bolsa para que la punta de la sonda este mirando hacia arriba. Rasgue totalmente la punta de la bolsa para abrirla.

4. Lentamente, introduzca la sonda en la uretra, deslizándola a través de la bolsa. La orina se vaciará dentro de la bolsa. Una vez que haya finalizado el flujo de la orina, retire la sonda 2 ó 3 cm. Si comienza de nuevo la evacuación de orina, espere unos segundos antes de retirar la sonda los próximos 1 ó 2 cm. Cuando la vejiga se haya vaciado, retire con cuidado la sonda, insertándola de nuevo en la bolsa.

5. Cierre la bolsa haciendo un nudo en la punta abierta.

6. Descarte la bolsa en un contenedor destinado a este fin, o rásguela por la zona indicada para poder vaciarla.

Producto de un sólo uso.

No reutilizar ni reesterilizar el producto.

Coloplast no aceptará responsabilidad alguna, si el uso de este producto es otro al indicado en las instrucciones de uso.

LoFric®Single Use Urinary Catheter

Retail label:

7 392532 013362

Type: MALE FR: 12

REF: 901240 LOT: 5462 Quantity: 25

SHOULD BE USED BEFORE
UTILIZAR ANTES DE

CE 0088

2004-06

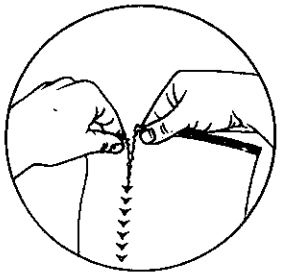
Inner package label:

LoFric®

REF 9012

LOT 5462

~~2004-06~~



IMPORTANT INSTRUCTION Contains drying agent sachet.
Do not eat.
WICHTIGER HINWEIS Päckchen enthält Feuchtigkeitsschutz.
Nicht zum Verzehr geeignet.
MODE D'UTILISATION Contient des substances déshydratantes.
Ne pas avaler.
BELANGRIJKE INSTRUCTIES Bevat zakje met droogstof. Niet eten.
VIKTIGT Innehåller påse med torkmedel. Får ej förtäras.
TÄRKEITÄ KÄYTTÖOHJEITA Sisältää kosteudenpoistajan.
Ei saa syödä.
IMPORTANTE Contiene sacchetto con agente essiccante. Non ingerire.
IMPORTANTE Contiene bolsita agente antihumedad. No ingerir.
VIKTIG Inneholder pose med tørremiddel. Må ikke spises.
VIGTIGT Indeholder pose med tørremiddel. Må ikke spises.

Packaging:
(In order to show all the labelling
the package is here cut into two)

LoFric®

SINGLE USE URINARY CATHETER

Blasenkatheter zum Einmalgebrauch
Sonde urinaire à usage unique
Urinkateter för engångsbruk
Kertakäyttöinen virtsakatetri
Catetere per urine monouso
Sonda urinaria desechable

Urinekatheter voor eenmalig gebruik
Urinkateter til engangsbruk
Engangskateter til blæretømning
Cathéter urinário descartável
Ουρολογικός καθετήρας μιας χρήσης

ETO gas sterilized
Mit Ethylenoxidgas sterilisiert
Stérilisé à l'oxyde d'éthylène
ETO-gas sterilizzato
Esterilizado por gas óxido de etileno

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

STERILE EO

CE 0088

ASTRA TECH

Astra Tech AB, Box 14, SE-431 21 Mölndal, Sweden

REF 9012

NELATON 12

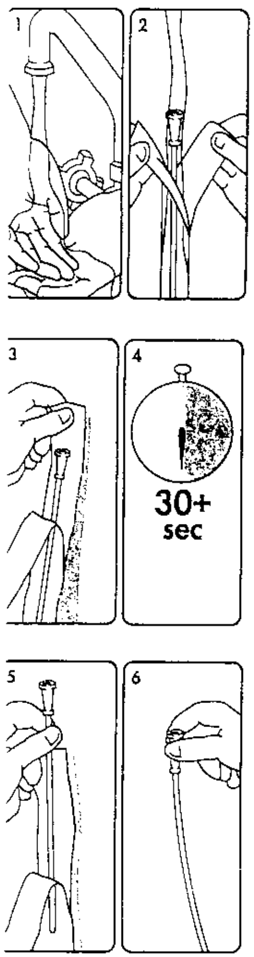
SHOULD BE USED BEFORE:
VERWENDBAR BIS:
UTILISER AVANT:
DOVREBBE ESSERE USATO PRIMA:
UTILIZAR ANTES DE:

2004-06

5462-911

LOT

90



INSTRUCTIONS

1. Wash your hands thoroughly.
2. Peel the packet open at the funnel end and fill with water (at home from the cold tap, in hospital sterile water or saline).
3. Remove the sticker at the top of the pack to reveal the self-adhesive patch and attach the pack to a dry surface.
4. Soak the catheter for at least 30 seconds whilst preparing yourself for catheterisation.
5. Remove the catheter from the pocket.
6. Carry out the catheterisation procedure as instructed. Dispose of the catheter sensibly after use.

NB. LoFric® is for single use only.

GEBRAUCHSINFORMATION

1. Waschen Sie Ihre Hände gründlich.
2. Die beiden Laschen am oberen Ende der Verpackung vorsichtig etwa 5–6 cm auseinanderziehen. Füllen Sie Flüssigkeit nach Anweisung Ihres Arztes, z.B. steriles Wasser (aqua dest.), physiologische Kochsalzlösung oder Trinkwasser in die Verpackung hinein.
3. Die Verpackung besitzt eine Klebeetikette. Entfernen Sie die blaue Schutzfolie und hängen Sie die Verpackung am Waschbecken, Nachttisch etc. auf. Sie können die gefüllte Packung auch in ein geeignetes Gefäß stellen.
4. Warten Sie 30 Sekunden. Danach ist der Katheter gleitfähig. In dieser Zeit können Sie Ihre Katheterisierung vorbereiten.
5. Entnehmen Sie den Katheter aus der Verpackung.
6. Führen Sie nun die Katheterisierung nach Anweisung Ihres Arztes durch. Entsorgen Sie den Katheter nach Gebrauch vorschriftsmäßig.

Anmerkung: Der LoFric® Katheter ist nur zum einmaligen Gebrauch bestimmt.

INSTRUCTIE

1. Was uw handen met water en zeep.
2. Trek de uiteinden van de katheterverpakking ongeveer 5 cm uit elkaar en vul de verpakking met water (thuis kunt u kraanwater gebruiken, in het ziekenhuis steriel water of een zoutoplossing).
3. Verwijder het blauwe papiertje [illegible] de bovenzijde van de verpakking [illegible] Met behulp van het kleefla[illegible] u de verpakking ergens aan [illegible] plakken.
4. Laat het water minimaal 30 [illegible] op de katheter inwerken.
5. Haal de katheter uit de verpak[illegible]
6. Voer de katheterisatie uit zoa[illegible] geleerd heeft.

NB. De katheter is voor eenma[illegible] gebruik, dus gooi deze na gebr[illegible]

ΟΔΗΓΙΕΣ

1. Πλύνετε καλά τα χέρια [illegible]
2. Ανοίξτε τη συσκευασία [illegible] συγκολλημένο άκρο [illegible] την με νερό (στο σπίτ[illegible] του κρύου νερού, στο[illegible] με αποστειρωμένο νε[illegible] λογικό ορό).
3. Αφαιρέστε τη χρ[illegible] κόλλητη ετικέτ[illegible] πάνω μέρος τ[illegible] την κόλλα που [illegible] της, η συσκευ[illegible] ωθεί στα πλακ[illegible]
4. Εμβαπτ[illegible] τουλάχιστο[illegible] ετοιμάζ[illegible]
5. Αφαιρέσ[illegible] συσκευ[illegible]
6. Προχ[illegible]

[illegible]

MODE D'EMPLOI

1. Se laver les mains.
2. Ouvrir l'emballage avec précaution et ajouter l'eau (utiliser de l'eau du robinet à domicile, et de l'eau stérile en milieu hospitalier).
3. [illegible] la bande adhésive bleue et [illegible] l'emballage sur le lavabo ou [illegible]

[illegible]

INSTRUKSJON

[illegible]

ANVÄNDARANVISNING

1. Tvätta händerna.
2. Öppna försiktigt förpackningen genom att dra isär flikarna i änden ca 5–6 cm och fyll med vatten direkt i förpackningen (i hemmet kan vanligt kranvatten användas, på sjukhus sterilt vatten eller NaCl).
3. Tag bort den blå självhäftande etiketten i toppen av förpackningen och fäst den på handfatet, nattduksbordet etc.
4. Vänta minst 30 sek.
5. Tag LoFric® ur förpackningen
6. Genomför kateteriseringen enligt förskrivares instruktion. Kasta katetern efter användning.

NB. LoFric® är endast avsedd för engångsbruk.

INSTRUKTION

1. Vask hænderne med vand og sæbe.
2. Fyld væske direkte i posen (postevand til hjemmebrug, sterilt vand eller fysiologisk saltvand på sygehuset).
3. Posen har et selvklæbende stykke tape som gør, at den kan hænge på f.eks. vask, sengebord etc.
4. Kateteret skal være i væsken i mindst 30 sekunder. Benyt tiden til at gøre dig klar til kateteriseringen.
5. Tag kateteret op af posen.
6. Kateteriser på sædvanlig vis. Smid kateteret ud efter brug.

NB. LoFric® er fremstillet til engangsbrug.

KÄYTTÖOHJE

1. Pese kätesi huolellisesti.
2. Avaa katetripakkaus värikoodatun suppilon puoleisesta päästä vetämällä liuskat erilleen 5–6 cm:n verran. Täytä pakkaus vedellä. (Kotona voit käyttää tavallista vesijohtovettä, sairaalaolosuhteissa suositellaan steriiliä vettä.)
3. Pakkauksessa on tarraliuska. Irrota sininen suojapaperi ja kiinnitä pakkaus sopivaan paikkaan esim. seinään tai pesualtaan reunaan.
4. Anna LoFric® katetrin liota vähintään 30 sekunnin ajan.
5. Ota katetri pakkauksesta ja katetroi.
6. Noudata saamiasi katetrointiohjeita. Heitä katetri käytön jälkeen roskiin.

LoFric® on kertakäyttöinen.

INSTRUÇÕES DE USO

1. Lave rigorosamente as mãos.
2. Abra o pacote pela extremidade do funil e encha com água (em casa, da torneira de água fria; no hospital, com água esterilizada ou salina).
3. Retire o aderente colorido, existente no lado de cima do pacote, que poderá deste modo ser fixado através da base adesiva, a ladrilhos ou ao lavatório.
4. Molhe o catéter durante, pelo menos, 30 segundos, enquanto se prepara para a cateterização.
5. Retire o catéter do pacote.
6. Leve a efeito a cateterização, conforme as instruções do médico receitante. Deite fora o catéter depois de usado.

Note bem: o LoFric® é apênas para uso individual.

ISTRUZIONI PER L'USO

1. Lavate accuratamente le mani.
2. Aprite la confezione dalla parte dell'imbuto e riempite con acqua (a casa con acqua fredda di rubinetto, in ospedale con acqua sterile o soluzione salina).
3. Rimuovete l'etichetta colorata in cima alla confezione, e con l'adesivo potete fissare la confezione alle mattonelle oppure al lavandino.
4. Lasciate il catetere immerso nell'acqua per almeno 30 secondi mentre vi preparate per il cateterismo.
5. Togliete il catetere dalla confezione.
6. Eseguite il cateterismo seguendo le istruzioni del vostro prescrittore. Gettate il catetere dopo l'uso.

N.B.: LoFric® è solo monouso.

INSTRUCCIONES DE USO

1. Lave sus manos cuidadosamente.
2. Abrir el envoltorio separando las lengüetas termoselladas de la parte superior del mismo y llenar con agua (en casa agua del grifo, en el hospital agua estéril o suero salino).
3. Retire el protector coloreado de la parte superior. Con el adhesivo descubierto puede fijar el envoltorio en las baldosas o en el lavabo.
4. Mantenga la sonda sumergida en agua al menos 30 segundos mientras se prepara para el sondaje.
5. Retire la sonda del envoltorio.
6. Proceda con el sondaje tal y como le enseñaron. Deseche la sonda debidamente después de usarla.

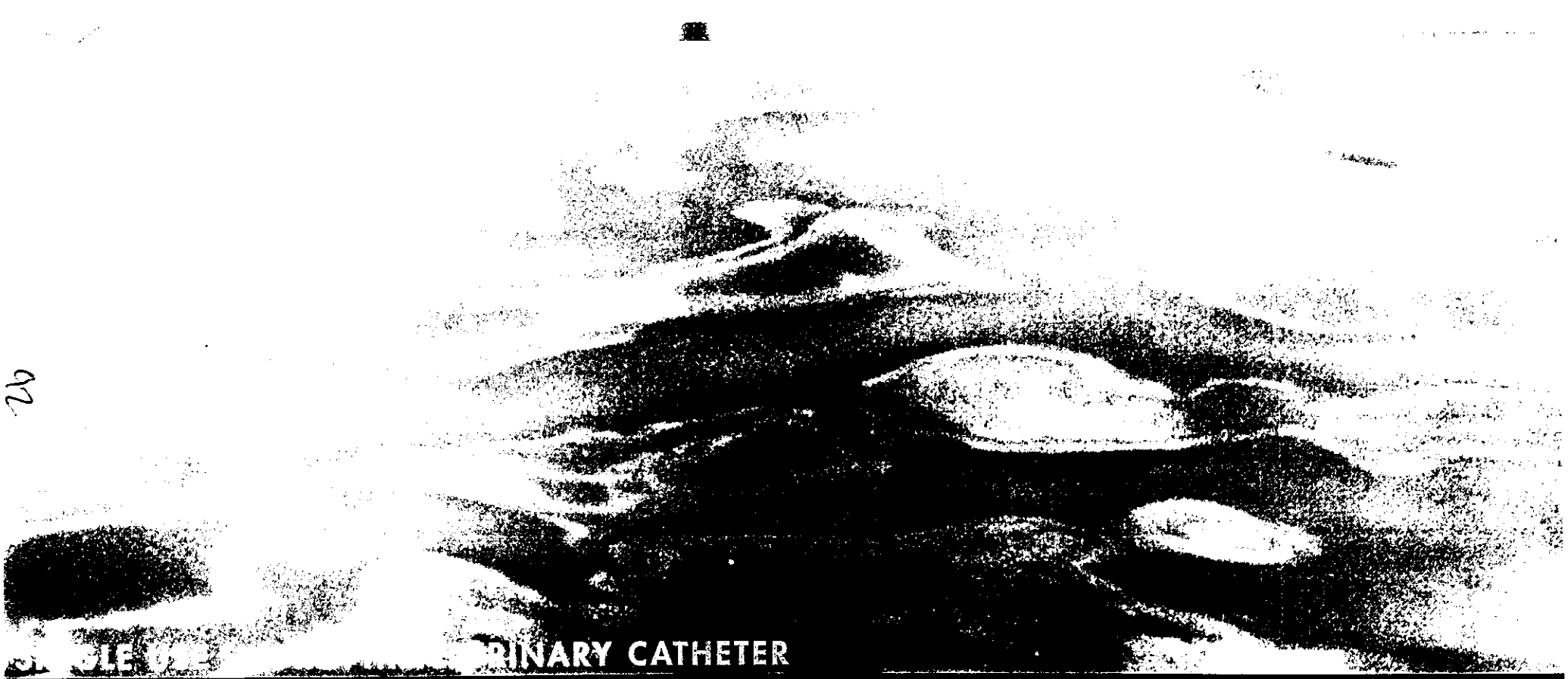
Tenga en cuenta que LoFric® es de un solo uso.

ASTRA
ASTRA TECH

A company in the AstraZeneca Group

Astra Tech AB, Box 14, SE-431 21 Mölndal, Sweden

91



RINARY CATHETER

Hydrophiler Blasenkatheter zum Einmalgebrauch
Sonde urinaire hydrophile à usage unique
Hydrofil urinkateter för engångsbruk
Kertakäyttöinen vesivaippakatetri
Catetere idrofilo monouso autolubrificante per cateterismo urinario
Sonda hidrofílica de uso único
Hydrofiele blaaskatheter voor eenmalig gebruik
Hydrofilt kateter til engangsbruk
Hydrofilt éngangskateter til blæretømning
Catéter urinário hidrofilo descartável "monouso"
Υδρόφιλος ουρολογικός καθετήρας μίας χρήσης

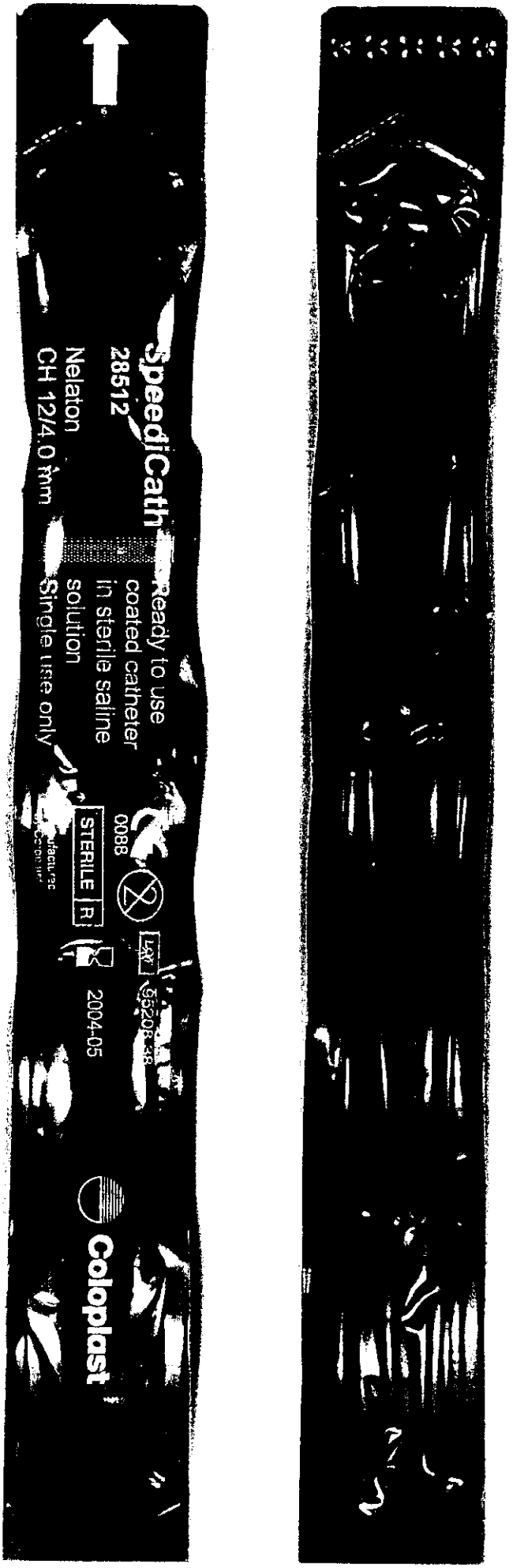
LoFric®

IMPORTANT INSTRUCTIONS	Store in a dry place at room temperature. Do not use the catheter if the individual pack is open or damaged
WICHTIGER HINWEIS	Bei Raumtemperatur trocken lagern. Bitte verwenden Sie den Katheter nicht, wenn die Packung offen oder beschädigt ist
MODE D'UTILISATION	A conserver au sec, à température ambiante. Ne pas utiliser la sonde si l'emballage individuel est ouvert ou abimé
VIKTIGT	Förvaras torrt i rumstemperatur. Använd inte katetern om enskyddsförpackningen är skadad eller bruten
TÄRKEITÄ KÄYTTÖOHJEITA	Säilytettävä kuivassa ja huoneen lämpötilassa. Älä käytä katetria jos pakkaus on avattu tai vaurioitunut
IMPORTANTE	Conservare in luogo asciutto a temperatura ambiente. Non usare il catetere se il blister che lo contiene è aperto o danneggiato
IMPORTANTE	Almacenar en lugar seco a temperatura ambiente. No utilizar la sonda si el envase unitario está abierto o dañado
BELANGRIJKE INSTRUCTIES	Droog bewaren bij kamertemperatuur. Gebruik de katheter niet wanneer de verpakking open of beschadigd is
VIKTIG	Oppbevares tørt i romtemperatur. Bruk ikke kateteret hvis den individuelle forpakningen er åpnet eller skadet
VIGTIGT	Skal opbevares tørt ved stuetemperatur. Anvend ikke kateteret, hvis pakningen er beskadiget eller brudt
INSTRUCÕES IMPORTANTES	Guardar em local seco a temperatura ambiente. Não usar o cateter se a embalagem individual estiver aberta ou deteriorada

SECTION 6: Proposed SpeediCath Labeling

Proposed foil packaging, carton labels and instructions for use for SpeediCath are provided on the following pages.

Foil packaging:
(Front and back)



Combined address and retail label:

SpeediCath Catheter

28412

Ready to use coated catheter
placed in sterile saline solution
For single use
Male
30 Pieces
Ch 12/4.0 mm

To be kept dry

STERILE A

5 701780 757010

06093
Coloplast Corp.
1955 West Oak Circle
Marietta
Georgia 30062

Toll Free Telephone:

Made in Denmark

LOT 12345.12

2003-06

CE 0088

(01)05701780757010(17)030600(10)12345:2

Shipper label:

Coloplast Corp. - Georgia, US **06093**

No. 284120

SpeediCath Catheter
Ready to use coated catheter
For single use - Male
Ch 12/4.0 mm
10 x 30 Pieces

Coloplast A/S

LOT **12345.12**

2003-06

STERILE R

CE 0088

5 701780 757027

(01)05701780757027(17)030600(10)01234512(93)5002

95

SpeediCath Catheter
he ready-to-use
coated catheter
female/male
Coloplast

SpeediCath Catheter

The new generation of ready-to-use coated catheters placed in a saline solution

Coloplast's new catheter concept, **SpeediCath,** consists of a coated non-PVC, ready-to-use catheter supplied in a saline solution.

The **SpeediCath** catheter is for single use only, and must then be discarded.

If the inner packaging is open or broken, do not use the catheter and do not try to re-sterilise it.

We recommend storing catheters at room temperature. However, exposure to extreme temperatures (below 0°C and above 50°C) for up to 24 hours will not damage the catheters.

Self-catheterisation is a common and reliable procedure, however it is important that you see your own specialist to receive professional guidance, and also ensure that you carefully follow these instructions.

Caution
The solution in which the catheter is stored is harmless, however care should be taken as it may stain your clothes.

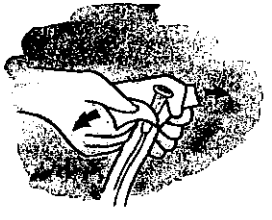
Coloplast accepts no liability for injury or loss that may arise if this product is not used entirely according to the company's recommendations.

NB! Self-catheterisation using a **SpeediCath** catheter should only be carried out under medical advice and on the order of a physician/Nurse and only in accordance with the instructions given.

In case of urinary tract infection with symptoms such as fever, discomfort on emptying the bladder, frequent need to empty the bladder or blood in the urine, contact your physician/Nurse.

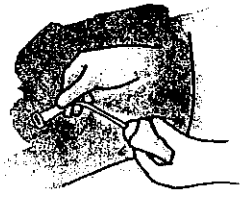
How to use SpeediCath:

Begin by washing your hands and the area around the urethral orifice. It is important to avoid transferring bacteria from your hands to the catheter. The packaging contains the coated catheter in a saline solution. Before you attempt to open the catheter ensure you are completely ready to proceed with the catheterisation.



Open the inner packaging by pulling on the tab indicated by the arrow. Take out the SpeediCath catheter which is ready to use.

Male



Lift your penis with one hand to straighten out your urethra.

Use your other hand to insert the catheter into the urethra approx. 2 cm at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter. Do not squeeze the penis, as this may make insertion of the catheter more difficult.

Female

Part your labia with one hand to expose the urethral orifice. Use your other hand to insert the catheter gently into the urethra, approx. 2 cm at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter.

Continue to insert the catheter into the urethra until urine starts to flow. If there is no toilet nearby, you can connect the catheter to a urine bag or other collecting device. When the urine stops flowing, ease out the catheter 2 to 3 cm. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1 to 2 cm. When the bladder is completely empty, slowly remove the catheter and dispose of hygienically.

SpeediCath Catheter

Ready-to-use coated catheter

STERILE R

CH	Catheter Nelaton male ♂	Catheter Tiemann male ♂	Catheter Nelaton female ♀	Catheter Nelaton pediatric	Catheter Nelaton - 30 cm
6			28506	28706	28606
8	28408		28508	28708	28608
10	28410	28490	28510	28710	28610
12	28412	28492	28512		28612
14	28414	28494	28514		
16	28416		28516		
18	28418				

CE 0088

Printed in Denmark by Anton M Jensen

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Coloplast

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark

Distributed by:
Coloplast Corp.
Marietta, GA 30062-2249
(770) 281-8400

SECTION 7: Biocompatibility Assessment

The safety of SpeediCath has been established in the following studies:
(Copies of relevant pages of reports are attached, see next page)

Results:

Test	Reference	Results
Intracutaneous Test in the Rabbit	Scantox, DK Lab no.46511	"Negligible" according to ISO 10993, Part 10, Section 5.4.
Systemic Injection Test in the Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity, meeting the requirements of USP 24 (2000).
Vaginal Irritation Test – ISO Method	Sterilization Technical Services, USA Test no. T02-1551	Meets the requirements of Vaginal Irritation Test ISO Method (ISO 10993-10:1995).
Test for Delayed Contact Hypersensitivity Using the Guinea Pig Maximization Test	Scantox, DK Lab no. 46510	No evidence of delayed contact hypersensitivity according to ISO 10993, Part 10.
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK 46508	Passed the requirements of USP 24 (cytotoxicity grade ≤2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements of USP 25 (cytotoxicity grade ≤2)
Ames test	Scantox, DK Lab no. 48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonised Guidelines (1995 and 1997))

Conclusion: Passed all tests.

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

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(b)(4) Third Party Information

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(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

SECTION 8: Sterilization Information

(b)(4)

K023254

ADDITONAL INFORMATION MEMORANDUM

Reviewer: Mary E. O'Brien, RN, MSN **Division/Branch:** DRARD/ULDB
Date: January 24, 2003

Trade Name: SpeediCath

Common Name: Urinary Catheter for Intermittent Use
Classification: 876.5130, II **ProCode:** GBM **Panel:** 78

Product To Which Compared:
K012374 Astra Tech LoFric® Plus Single Use Urinary Catheter
K896750 Astra Tech LoFric® Single Use Urinary Catheter
K973070 Coloplast Conveen EasiCath Set

Contact: Elizabeth Boots **Phone:** 507-386-4362
Quality Assurance Vice President **FAX:** 507-345-3291

Sponsor: Coloplast Corp.
1940 Commerce Drive
North Mankato, MN 56003

SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

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

n addition to completing the form, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

NARRATIVE DEVICE DESCRIPTION

INTENDED USE:

The SpeediCath Catheter is indicated for use by patients with chronic urine retention and patients with as post void residual volume (PVR) due to neurogenic and non neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

DEVICE DESCRIPTION:

The SpeediCath Catheter is a single use, disposable polyurethane catheter. It is coated and placed in a saline solution, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

The catheter comes in a 200 mm length (female and pediatric), 300 mm length (boy) and 400 mm length (male and Tiemann). The French sizes are as follows: Female and Male 6, 8, 10, 12, 14, 16; Tiemann 10, 12, 14; Pediatric 6, 8, 10; and Boy 6, 8, 10, 12.

MATERIALS:

The coating on the catheter consists of one layer and is composed of the following materials:

Polyvinylpyrrolidone (PVP)
(b)(4) [redacted]

Salt (NaCl)
(b)(4) [redacted]

(b)(4) [redacted]

The saline solution in the foil bag (b)(4) [redacted]. The saline solution also contains polyvinylpyrrolidone to maintain the (b)(4) [redacted]. The PVP ensures the low friction of the catheter.

PERFORMANCE TESTING:

The SpeediCath Catheter are similar to predicate catheters that have been presented in the application, (b)(4) [redacted]

[redacted]

BIOCOMPATIBILITY TESTING:

The SpeediCath Catheter has passed all pertinent biocompatibility tests, and are summarized below.

SpeediCath Biocompatibility Testing

Test	Reference	Results
Intracutaneous Test in Rabbit	Scantox, DK Lab no.46511	"Negligible" ISO 10993, Part 10, Sec 5.4
Systemic Inj. Test in Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity USP 24 (2000)
Vaginal Irritation Test -ISO	Sterilization Tech Servs, USA Test no. T02-1551	Meets requirements (ISO 10993-10:1995)
DelayedContact Hypersensitivity in Guinea Pig Maximization Test	Scantox, DK Lab no.46510	No evidence of delayed contact (ISO 10993, Part 10)
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK Lab no.46508	Passed requirements USP 25 (Cytotoxicity grade ≤ 2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements USP 25 (Cytotoxicity grade ≤ 2).
Ames test	Scantox, DK Lab no.48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonized Guidelines (1995 and 1997)

LABELING:

Labeling has been provided which includes instructions for use. (b)(4) [redacted]

STERILITY INFORMATION:

Sterility information:
a. Method: (b)(4) [redacted]

b. Dose: (b)(4)
c. SAL: (b)(4)
d. Packaging: foil peel pack

The sterility information provided for this device is adequate.

ADMINISTRATIVE REQUIREMENTS:

Indications for Use (Page 12), Truthful and Accurate Statement (Page 14), 510(k) Summary (Page 19 – 22) have been provided and have been found to be accurate.

DEVICE SUMMARY:

	Yes	No
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 single use?	☑	☐
Is the device home use?	☑	
Is the device for prescription?	☑	☐
Does the device contain a drug or biological product as a component?		☑
Is this device a kit?	☐	☑

SUBSTANTIAL EQUIVALENCE:

The SpeediCath Catheters have similar intended use and design as the K012374 Astra Tech LoFric® Plus Single Use Urinary Catheter cleared under (K012374), the Astra Tech LoFric® Single Use Urinary Catheter cleared under (K896750), and the Coloplast Conveen EasiCath Set cleared under (K973070). The SpeediCath Catheter has met the performance criteria according to ASTM 623-89 and has passed all pertinent biocompatibility tests. Therefore, there are no issues within this application that would affect the safety and effectiveness of these devices.

RECOMMENDATION:

Substantially equivalent to other Class II devices described in 21 CFR § 876.5130, Urological Catheter and Accessories, Catheter Urethral.

Mary E. O'Brien, RN, MSN
Division of Reproductive, Abdominal,
and Radiological Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Mary Ellen Rutkowski

Subject: 510(k) Number K023254

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

☐ Refused to accept.

☒ Requires additional information (other than refuse to accept): Telephone 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):

~~II, 876.5160, GBM, 78~~

Review: Anna M. Thrall (Branch Chief) ULOB (Branch Code) 12/20/02 (Date)

Final Review: _____ (Division Director) _____ (Date)

Revised:8/17//99

K023254

ADDITONAL INFORMATION MEMORANDUM

Reviewer: Mary E. O'Brien, RN, MSN **Division/Branch:** DRARD/ULDB
Date: December 16, 2002

Trade Name: SpeediCath

Common Name: Urinary Catheter for Intermittent Use
Classification: 876.5130, II **ProCode:** GBM **Panel:** 78

Product To Which Compared:
K012374 Astra Tech LoFric® Plus Single Use Urinary Catheter
K896750 Astra Tech LoFric® Single Use Urinary Catheter
K973070 Coloplast Conveen EasiCath Set

Contact: Elizabeth Boots **Phone:** 507-386-4362
Quality Assurance Vice President **FAX:** 507-345-3291
Sponsor: Coloplast Corp.
1940 Commerce Drive
North Mankato, MN 56003

NARRATIVE DEVICE DESCRIPTION

INTENDED USE:

The SpeediCath Catheter is indicated for use by patients with chronic urine retention and patients with as post void residual volume (PVR) due to neurogenic and non neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

DEVICE DESCRIPTION:

The SpeediCath Catheter is a single use, disposable polyurethane catheter. It is coated and placed in a saline solution, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

The catheter comes in a 200 mm length (female and pediatric), 300 mm length (boy) and 400 mm length (male and Tiemann). The French sizes are as follows: Female and Male 6, 8, 10, 12, 14, 16; Tiemann 10, 12, 14; Pediatric 6, 8, 10; and Boy 6, 8, 10, 12.

MATERIALS:

The coating on the catheter consists of one layer and is composed of the following materials:

Polyvinylpyrrolidone (PVP)

(b)(4) [redacted]

Salt (NaCl)

(b)(4) [redacted]

(b)(4) [redacted]

The saline solution in the foil bag ensures (b)(4) [redacted]. The saline solution also contains polyvinylpyrrolidone to maintain the (b)(4) [redacted] The PVP ensures the low friction of the catheter.

PERFORMANCE TESTING:

The SpeediCath Catheter are similar to predicate catheters that have been presented in the application, however, performance testing is necessary for this device.

BIOCOMPATIBILITY TESTING:

The SpeediCath Catheter has passed all pertinent biocompatibility tests, and are summarized below.

SpeediCath Biocompatibility Testing

Test	Reference	Results
Intracutaneous Test in Rabbit	Scantox, DK Lab no.46511	"Negligible" ISO 10993, Part 10, Sec 5.4
Systemic Inj. Test in Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity USP 24 (2000)
Vaginal Irritation Test -ISO	Sterilization Tech Servs, USA Test no. T02-1551	Meets requirements (ISO 10993-10:1995)
DelayedContact Hypersensitivity in Guinea Pig Maximization Test	Scantox, DK Lab no.46510	No evidence of delayed contact (ISO 10993, Part 10)
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK Lab no.46508	Passed requirements USP 25 (Cytotoxicity grade ≤ 2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements USP 25 (Cytotoxicity grade ≤ 2).
Ames test	Scantox, DK Lab no.48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonized Guidelines (1995 and 1997)

LABELING:

Labeling has been provided which includes instructions for use. (b)(4) [redacted]

STERILITY INFORMATION:

Sterility information:
a. Method (b)(4) [redacted]
b. Dose: (b) [redacted]
c. SAL: [redacted]
d. Packaging: foil peel pack

The sterility information provided for this device is adequate.

ADMINISTRATIVE REQUIREMENTS:

Indications for Use (Page 12), Truthful and Accurate Statement (Page 14), 510(k) Summary (Page 19 – 22) have been provided and have been found to be accurate.

RECOMMENDATION:

This application will be placed on hold until the performance testing is obtained.

Mary E. O'Brien, RN, MSN
Division of Reproductive, Abdominal,
and Radiological Devices

Division of Reproductive, Abdominal,
and Radiological Devices
HFZ-470
DHHS/PHS/FDA/CDRH/ODE
9200 Corporate Blvd.
Rockville, MD 20850

From: Mary Beth O'Brien, RN, MSN
Phone No.: (301) 594-2194 EXT. 126
FAX No.: (301) 594-2339
Email: moa@cdrh.fda.gov

TO: Ms. Elizabeth Boots **FAX:** 507-345-3291

SUBJECT: (K023254) SpeediCath

Comments: December 23, 2002

Dear Ms. Boots,

After discussion of your device with the Brach Chief of Urology performacne testing (b)(4) (b)(4)

(b)(4)

You may refer to our *Guidance for the Content of Premarket Notification for Conventional and Antimicrobol Foley Catheters.*

Your application will be placed on hold until the performance testing is obtained.

Sincerely,

Mary Beth O'Brien RN, MSN

Number of Pages: 1 (Including cover sheet. Please advise if transmission is illegible.
"This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone and return it to us at the above address by mail. Thank you."

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	0897
CONNECTION TEL	915073453291
SUBADDRESS	
CONNECTION ID	COLOPLAST CORP.
ST. TIME	12/23 10:55
USAGE T	00'30
PGS. SENT	1
RESULT	OK

Sponsor called on 12/20/02 that application would be on hold until (b)(4) (b)(4) MOA

Coloplast Corp.
1940 Commerce Drive
N. Mankato, MN 56002-8300

Telephone (507) 345-6200
Fax (507) 345-3291

Coloplast

Fax

To	**Mary Beth O'Brien**	From	**Betty Boots**
Fax number	**301-594-2339**	Number of pages including cover page	**3**
Date	**December 20, 2002**	If you do not receive all pages, please call	**507-386-4362**

Here is the updated IFU with the wording we discussed added. It is just past half way down on the left column.

Hope you have Happy Holidays.

Elizabeth Boots

Elizabeth Boots
VP, QA

Notice of Confidentiality

The attached documents to this cover page contain information which is confidential and legally privileged. This information is intended solely for the use of the individual named as recipient above. All others are notified that any unauthorized copying, distribution, or disclosure of these materials, or the taking of any action in reliance thereof, is prohibited. If you have received this in error, please notify the sender immediately and follow the directions given to you for the safeguarding or destruction of the documents in question.

SpeediCath Catheter - Ready-to-use hydrophilic-coated catheter

FR	Catheter Nelaton male ♂	Catheter Tiemann male ♂	Catheter Nelaton female ♀	Catheter Nelaton pediatric 👶	Catheter Nelaton - 30 cm 👶			
6			28506	28706	28606			
8	28408		28508	28708	28608			
10	28410	28490	28510	28710	28610			
12	28412	28492	28512		28612			
14	28414	28494	28514					
16	28416		28516					
18	28418							

STERILE R

CE 0088

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Coloplast

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
Denmark

Distributed by:
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1955 West Oak Circle
Marietta, GA 30062-2249
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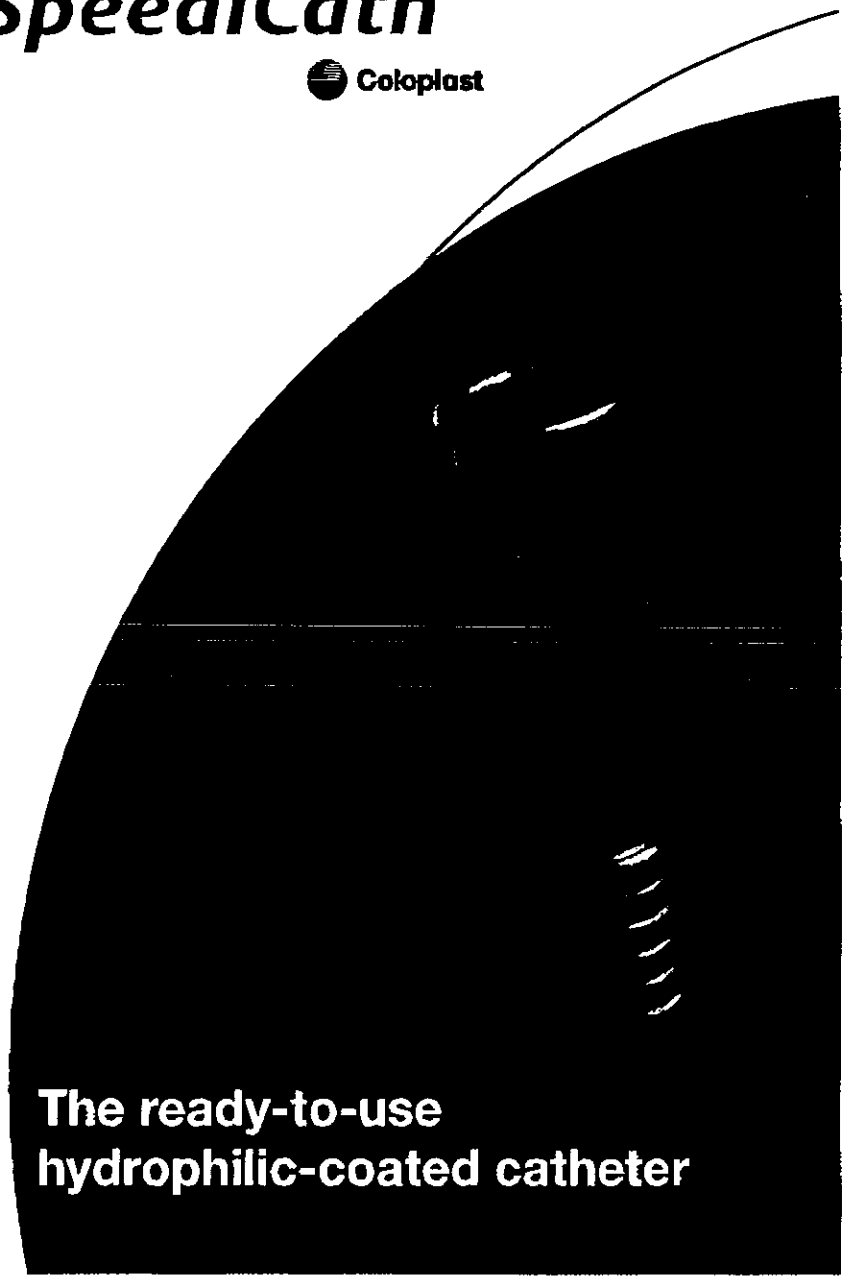
(770) 261-8400
www.us.coloplast.com

Coloplast Canada Corp.
3300 Ridgeway Drive
Unit 12
Mississauga, ON L5L 5Z9
Canada
800-533-0464

SpeediCath

Coloplast



The ready-to-use hydrophilic-coated catheter

12/20/02 FRI 10:44 FAX 507 345 3291 COLOPLAST CORP. 002

35

SpeediCath

The new generation of ready-to-use hydrophilic-coated catheters placed in a saline solution.

Coloplast has developed SpeediCath, a ready-to-use non-PVC, hydrophilic-coated catheter. SpeediCath is available for adults (male & female) and children (pediatrics).

SpeediCath is for single-use only and must be discarded after each use.

If the inner packaging is open or broken, do not use and immediately discard the product.

Do not attempt to re-sterilize the catheter.

SpeediCath should be stored at room temperature. Exposure to extreme temperatures (below 32°F and above 100°F) for up to 24 hours will not damage the catheters.

Self-catheterization is a common and reliable procedure. It is important for you to contact your physician or nurse in order to receive professional guidance. Please make sure to carefully follow the SpeediCath instructions in this booklet.

Caution
Federal (USA) law restricts the device to be sold only by or on order of a physician.

The saline solution is harmless, but may stain your clothes.

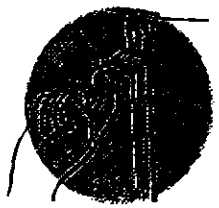
Coloplast accepts no liability for injury or loss that may arise if this product is not used according to the company's recommendations.

SpeediCath should be used only under prescription from your physician and in accordance with the instructions provided.

Immediately contact your physician or nurse in case of urinary tract infection, fever, discomfort emptying the bladder, frequent need to empty the bladder, or blood in the urine.

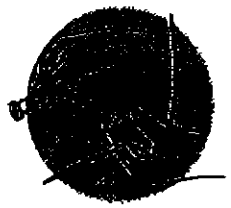
How to use SpeediCath

Begin by washing your hands and the area around the urethral orifice. It is important to avoid the transfer of bacteria from your hands to the catheter. The packaging contains the coated catheter in a saline solution. Before the package is opened, make sure you are ready to completely proceed with the catheterization. If stored vertically, turn the catheter to a horizontal position to make sure that the saline solution is distributed evenly, ensuring that the coating is fully saturated. A full saturation ensures optimum lubrication.



Open the inner packaging by pulling the ring. Take out the SpeediCath catheter which is ready to use.

Male



Lift your penis with one hand to straighten out your urethra.
Use your other hand to insert the catheter into the urethra approx. 2 cm at a time.
Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter.
Do not squeeze the penis, as this may make insertion of the catheter more difficult.

Female

Part your labia with one hand to expose the urethral orifice. Use your other hand to insert the catheter gently into the urethra, approx. 2 cm at a time. Just before the catheter reaches the bladder, you may feel a slight resistance from the sphincter.

Continue to insert the catheter into the urethra until urine starts to flow. SpeediCath can be attached to a urine bag or other collection device if there is no access to a toilet. When the urine stops flowing, ease out the catheter 2 to 3 cm. If the flow of urine restarts, wait a few seconds before easing out the catheter another 1 to 2 cm. When the bladder is completely empty, slowly remove the catheter and properly dispose of hygienically.

12/20/02 FRI 10:44 FAX 507 345 3291 COLOPLAST CORP. 003

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

510(k) Number: K023254

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.	✓ p3	
Truthful and Accurate Statement.	✓ p14	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓ pp8,16	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓ pp7,17	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	✓ pp51-52	
Statement of Indications for Use that is on a separate page in the premarket submission.	✓ p12	
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.	✓ p36-50	
510(k) Summary or 510(k) Statement.	✓ pp19-22	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	pp23,26	
Identification of legally marketed predicate device. *	✓ pp7,35	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		✓ ?
Class III Certification and Summary. **	NA	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	NA	
510(k) Kit Certification ***	NA	

* - 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.

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		

is posted with the 510(k) boilers 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 not 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 and 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.		

* - 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:	✓ pp.23-24, 27-34 pp.57	
b) Sterilization and expiration dating information:	p.37	
i) sterilization process	✓ β radiation	
ii) validation method of sterilization process	✓	
iii) SAL	✓ 10⁻⁶	
iv) packaging	✓	
v) specify pyrogen free	NA	
vi) ETO residues	NA	
vii) radiation dose	✓ 25.0 kGy	
c) Software Documentation:	NA	

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: Laura B. Reed
Concurrence by Review Branch: _____

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Mary Ellen Brennan Ripman

Subject: 510(k) Number K023254/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 N/A
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

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

This 510(k) contains:

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

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

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

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

Animal Tissue Source ☐ YES ☒ NO

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

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 days

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

II, 876.5130, GBM, 78

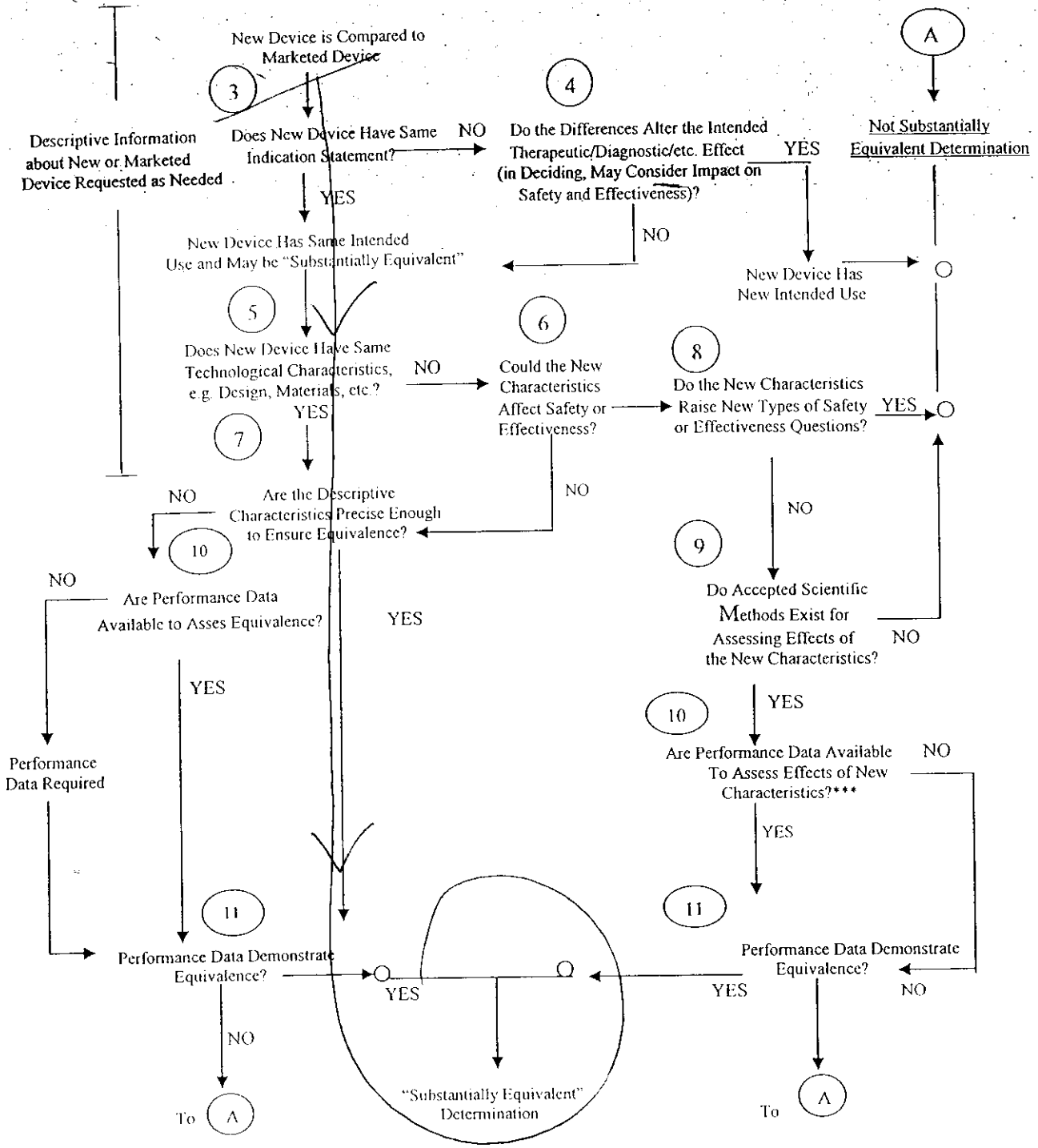
Review: [signature] (Branch Chief) CDRH (Branch Code) 1/27/03 (Date)

Final Review: [signature] (Division Director) 1/27 (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.

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

January 16, 2003

COLOPLAST CORP.
1940 COMMERCE DR.
NORTH MANKATO, MN 56003
ATTN: ELIZABETH BOOTS

510(k) Number: K023254
Product: SPEEDICATH

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

K023254/S1

Coloplast Corp.
1940 Commerce Drive
N. Mankato, MN 56002-8300

Telephone (507) 345-6200
Fax (507) 345-3291

Coloplast

January 15, 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

FDA/CDRH/ODE/DMC
2003 JAN 16 P 2:13

To Mary Beth O'Brian:

Reference: 510(k) K023254 SPEEDICATH

I am sending two copies of a summary of the requested performance data for SpeediCath along with a fax and letter requesting the information.

I may be reached at my direct dial line of 507-386-4362 or through the switchboard at 507-345-6200 for any comments or questions.

Sincerely,

Elizabeth Boots

Elizabeth Boots
Vice President Quality Assurance
Coloplast Corp
US Agent and Official Correspondent
Coloplast A/S

510(k) 11

Division of Reproductive, Abdominal,
and Radiological Devices
HFZ-470
DHHS/PHS/FDA/CDRH/ODE
9200 Corporate Blvd.
Rockville, MD 20850

From: Mary Beth O'Brien, RN, MSN
Phone No.: (301) 594-2194 EXT. 126
FAX No.: (301) 594-2339
Email: moa@cdrh.fda.gov

TO: Ms. Elizabeth Boots **FAX:** 507-345-3291

SUBJECT: (K023254) SpeediCath

Comments: December 23, 2002

Dear Ms. Boots,

After discussion of your device with the Brach Chief of Urology performacne testing (b)(4) [redacted]

(b)(4) [redacted]

You may refer to our *Guidance for the Content of Premarket Notification for Conventional and Antimicrobol Foley Catheters.*

Your application will be placed on hold until the performance testing is obtained.

Sincerely,

Mary Beth O'Brien RN, MSN

Number of Pages: 1 (Including cover sheet. Please advise if transmission is illegible.
"This document is intended only for the use of the party to whom it is addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone and return it to us at the above address by mail. Thank you."

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 23, 2002

COLOPLAST CORP.
1940 COMMERCE DR.
NORTH MANKATO, MN 56003
ATTN: ELIZABETH BOOTS

510(k) Number: K023254
Product: SPEEDICATH

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.

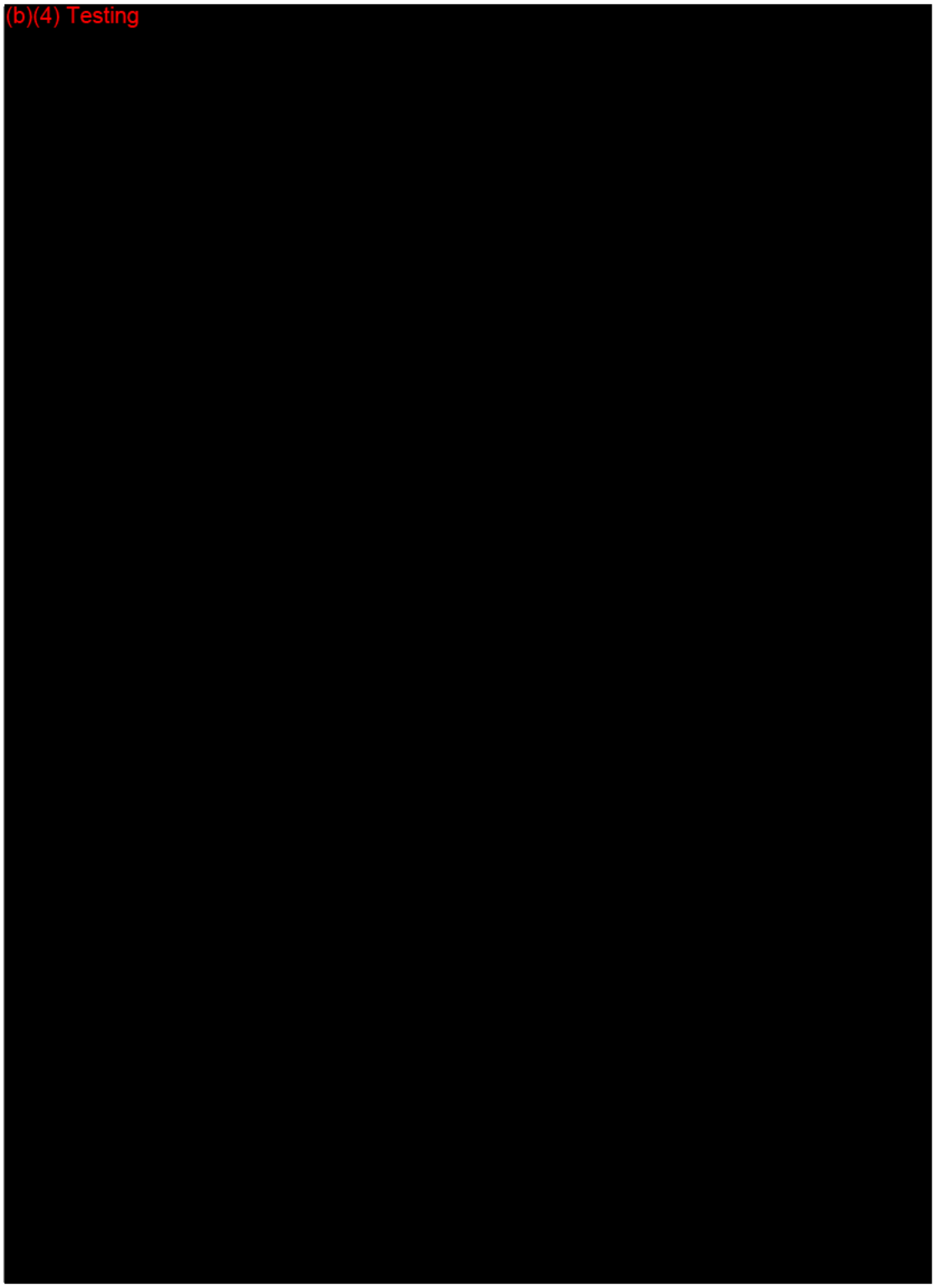
If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

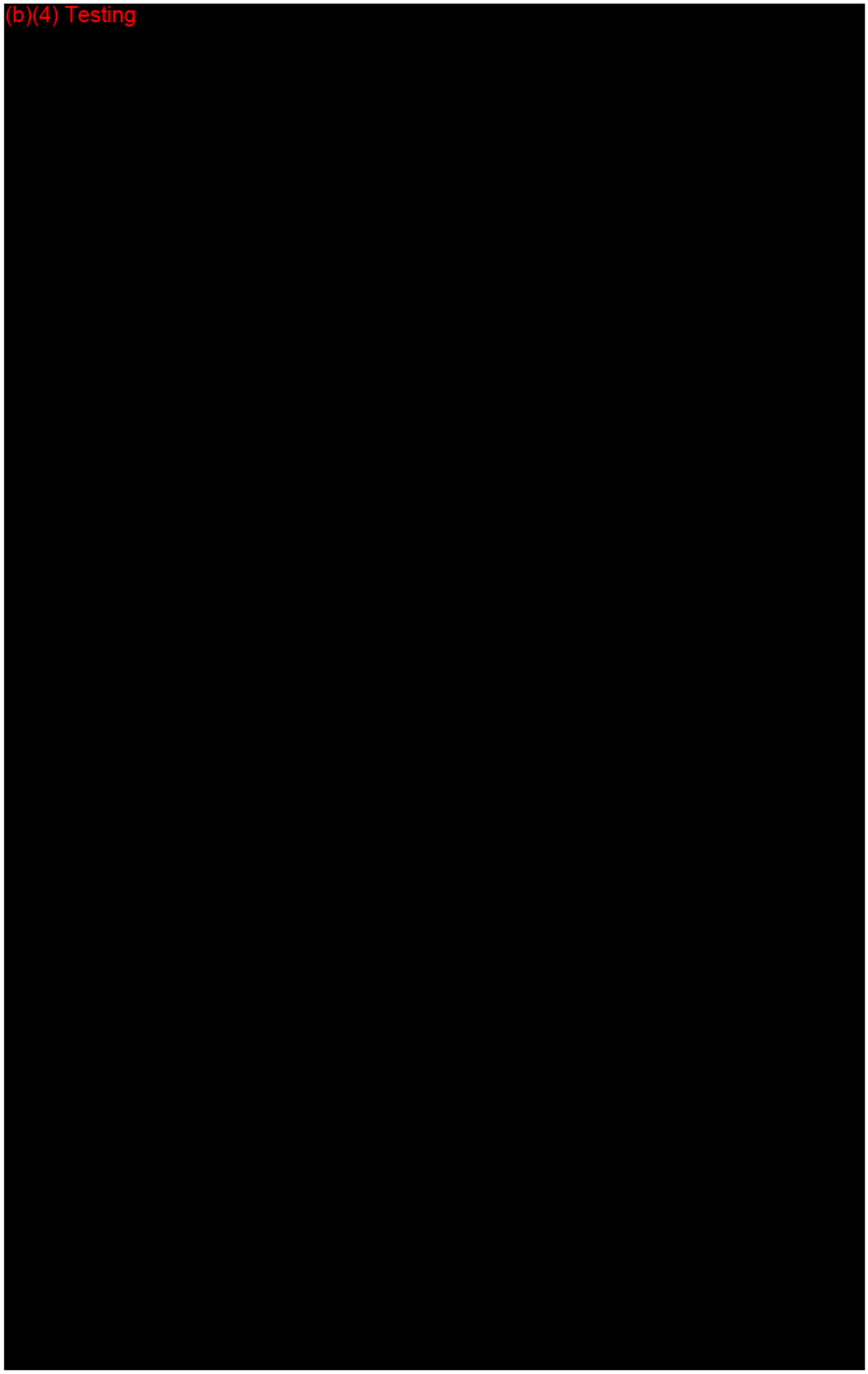
Sincerely yours,

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

Performance data

(b)(4) Testing

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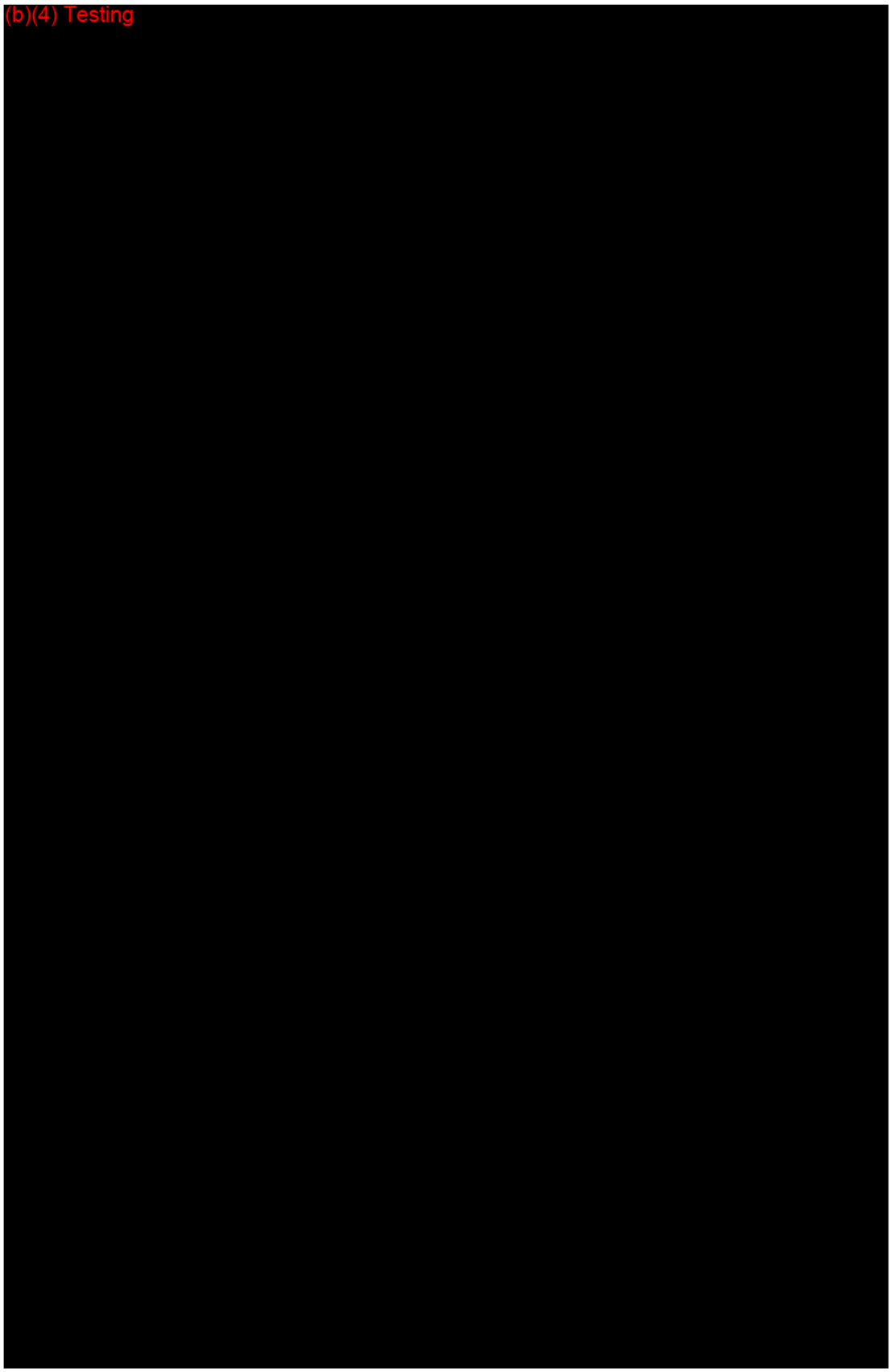

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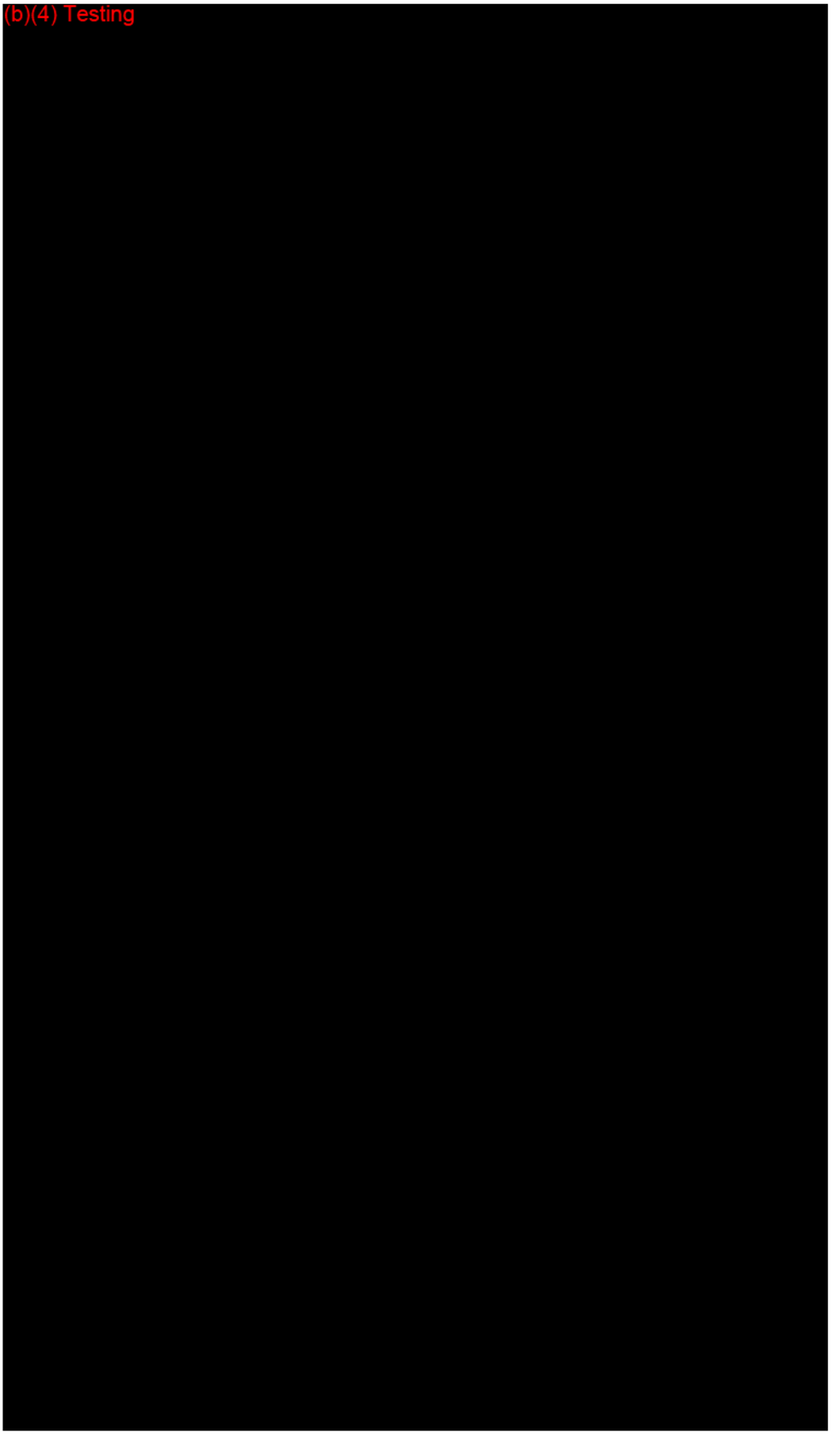

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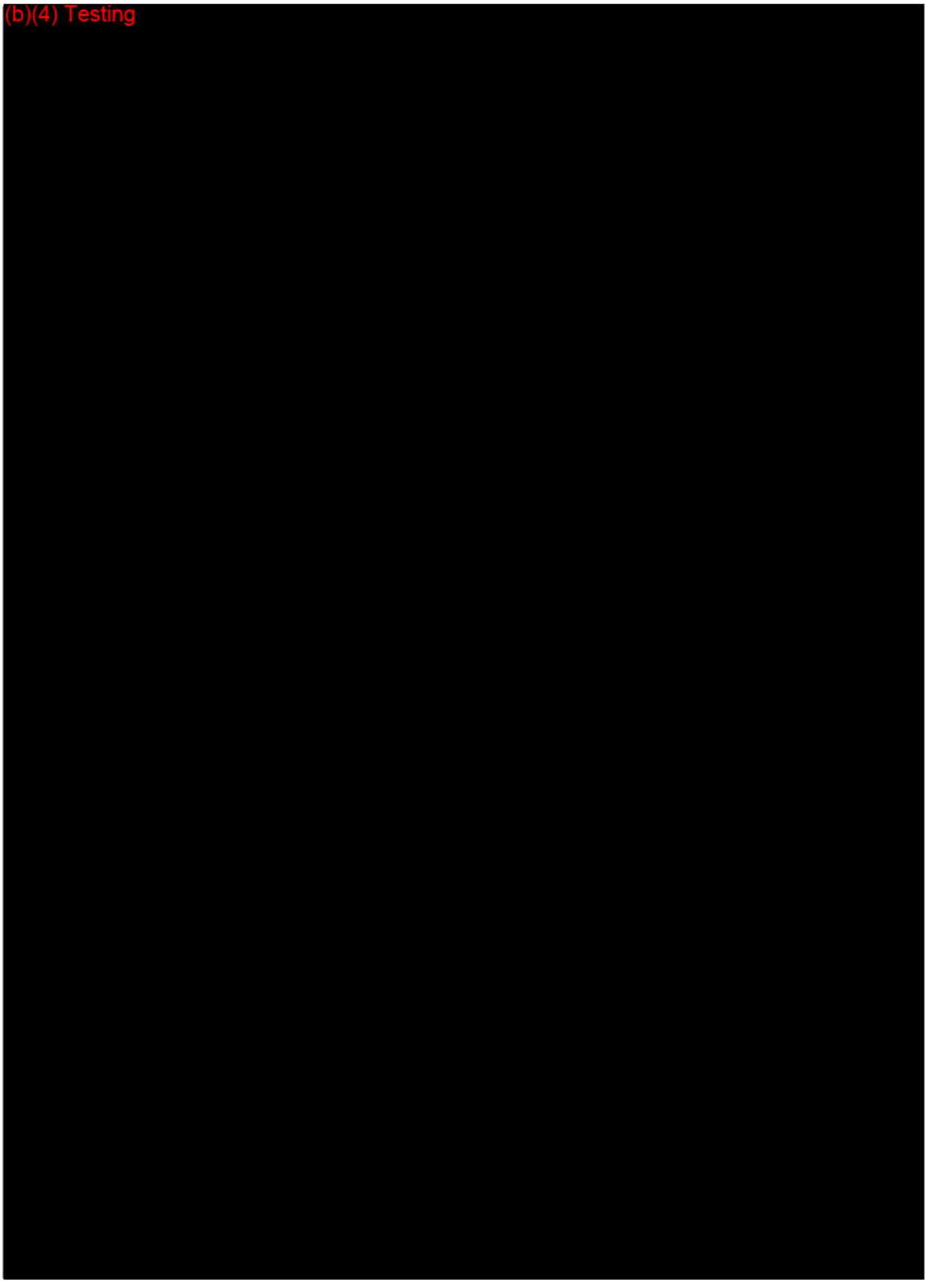
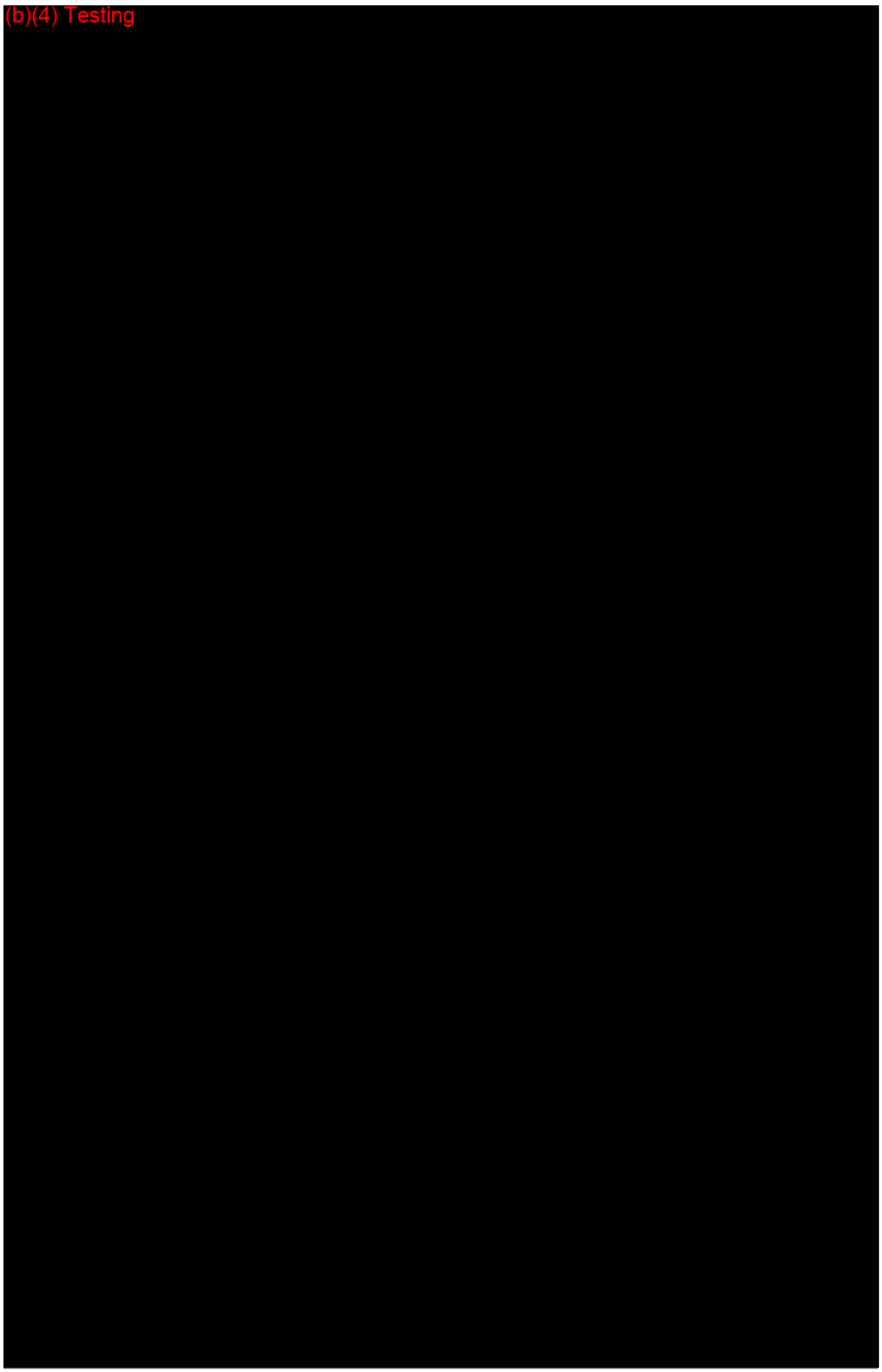


(b)(4) Testing



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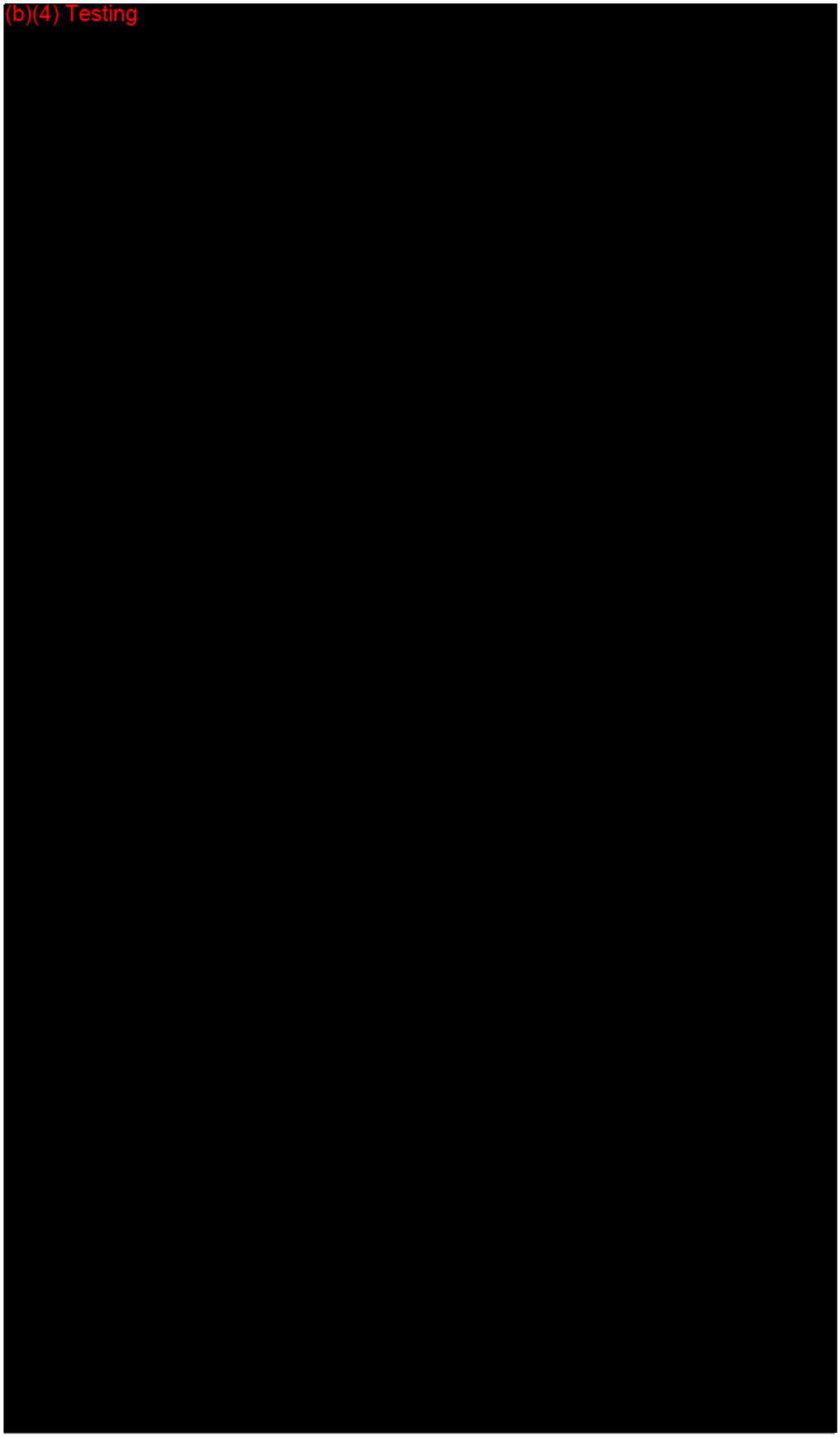

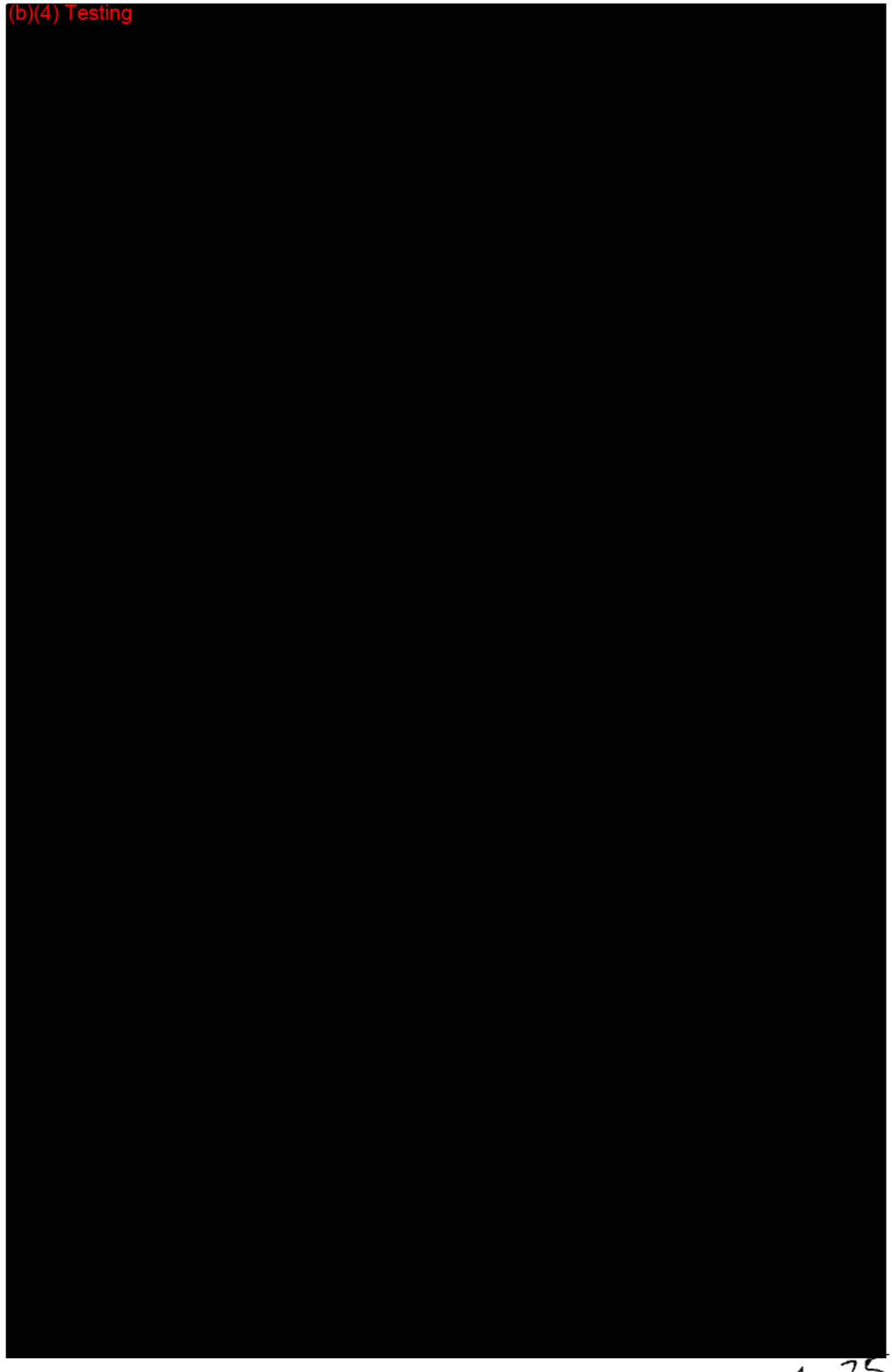
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