DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Anchor Products Company
% Mr. Robert H. Thrun
President
52 Official Road
Addison, Illinois 60101-4589

Re: K061555
Trade/Device Name: Anchor Tissue Retrieval System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 4, 2006
Received: August 17, 2006

Dear Mr. Thrun:

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 such 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 Section 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Peb Ma

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061555

Device Name: Anchor Tissue Retrieval System

Indications For Use:

The Anchor Tissue retrieval system is a sterile disposable pouch used with a dedicated introducer for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery.

Prescription Use __X_____ AND/OR Over-The-Counter Use

_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061555

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2006

Anchor Products Company
% Mr. Robert H. Thrun
President
52 Official Road
Addison, Illinois 60101-4589

Re: K061555
Trade/Device Name: Anchor Tissue Retrieval System
Regulation Number: 21 CFR 876.1500
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Sincerely yours,

for Pdl

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K061555

Device Name: Anchor Tissue Retrieval System

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The Anchor Tissue retrieval system is a sterile disposable pouch used with a dedicated introducer for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known):

Device Name:

Indications For Use:

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061555

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

June 28, 2006

ANCHOR PRODUCTS CO.
52 OFFICIAL RD.
ADDISON, IL 60101
ATTN: ROBERT H. THRUN

510(k) Number: K061555
Received: 27-JUN-2006
Product: ANCHOR LAPARSCOPIC TISSUE RETIEVAL SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) 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.

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 one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)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.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRHs eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
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

June 06, 2006

ANCHOR PRODUCTS CO.
52 OFFICIAL RD.
ADDISON, IL 60101
ATTN: ROBERT H. THRUN

510(k) Number: K061555
Received: 05-JUN-2006
Product: ANCHOR LAPARSCOPIC
User Fee ID Number: E RETIEVAL
SYSTEM

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier (e.g., Fed Ex, UPS, etc.)
Food and Drug Administration	U.S. Bank
P.O. Box 956733	956733
St. Louis, MO 63195-6733.	1005 Convention Plaza
	St. Louis, MO 63101
	(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at http://www.fda.gov/oc/mdufma.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file an application with FDA or what type of application to file, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)443-6597 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/cdrh/dsmamain.html, or you may submit a 513(g) request to the Document Mail Center at the address above. If you have any questions concerning the contents of this letter, you may contact me at (301) 594-1190.

Sincerely yours,

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

K061555

ANCHOR PRODUCTS COMPANY
52 Official Road, Addison, IL 60101-4589
Telephone *630/543-9124*
800/323-5134 *www.anchorsurgical.com*
FAX *630/543-9131* *Email: info@anchorsurgical.com*

June 1, 2006

K-49.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Dr.
Rockville, MD 20850

RE: Anchor Laparoscopic Tissue Retrieval Device
510(k) Notification

Anchor Products Company has redesigned its Anchor Laparascopic Tissue Retrieval System K982073. Enclosed are two copies of the 510(k) Summary of Anchor Products Company for Anchor Laparoscopic Tissue Retrieval System, as redesigned.

If you have any questions about this Summary or need any additional information, do not hesitate to contact me at 630/543-9124.

Sincerely,

Robert H. Thrun
President

RHT:j
Enclosures

GU 11/102

ANCHOR LAPAROSCOPIC TISSUE RETRIEVAL SYSTEM

Submitted To:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Dr.
Rockville, MD 20850

Submitted By:

Robert H. Thrun, President
Anchor Products Company
52 Official Road
Addison, IL 60101
630/543-9124

June 1, 2006

ANCHOR PRODUCTS COMPANY
52 Official Road, Addison, IL 60101-4589
Telephone *630/543-9124*
800/323-5134 *www.anchorsurgical.com*
FAX *630/543-9131* *Email: info@anchorsurgical.com*

June 1, 2006

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
1390 Piccard Dr.
Rockville, MD 20850

RE: 501(k) Notification - Anchor Laparoscopic Tissue Retrieval System

Anchor Products Company (Anchor) intends to market the Anchor Laparoscopic Tissue Retrieval System as redesigned. The prior device was approved in 1998 with the designation K982073.

1. Submitter

Anchor Products Company
Attn: Robert H. Thrun, President
52 Official Road
Addison, IL 60101
Telephone Number: 630/543.9124

2. Device Name

(a)	Trade name:	Anchor Laparoscopic Tissue Retrieval System
(b)	Common name:	Laparoscopic Specimen Bag
(c)	Classification name:	876-1500 Endoscope and Accessories
(d)	Classification:	Class II Gastroenterology-Urology
(f)	Prior Designation of Device:	K982073

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3. Redesign of Anchor Laparoscopic Tissue Retrieval Device

Anchor redesigned its Laparoscopic Tissue Retrieval Device as set forth in Exhibit A attached. This redesigned device performs the same function as device K982013; (b)(4)Trade Secret Process [redacted].

4. Device Description

The Anchor redesigned tissue retrieval system is a sterile disposable polyamide nylon pouch which can be used with an introducer tube and will be available in five pouch sizes: The retrieval pouch is designed to fit into a previously placed trocar entry port and is inserted into the body cavity using either an introducer or standard laparoscopic instruments. Under direct visual control, the retrieval pouch is opened so that the tissue sample or organ may be placed into it. A portion of the pouch is pulled out of the body cavity along with the entry port and introducer tube; however, the main body of the pouch containing the tissue sample or organ remains inside the abdominal cavity thereby allowing the surgeon to either withdraw the pouch with the tissue or organ through the previously made opening in the abdomen, or insert surgical instruments into the retrieval pouch to morcellate or cut the tissue or organ into small pieces for aspiration.

The Anchor tissue retrieval system is assembled, packaged, sterilized, and sold by Anchor Products Company. The device will be packaged in a tyvek/polyester film package and will bear a label, similar to that in Exhibit B. This device will be sold sterile. The sterilization protocol will be to SAL, 10-6 AAMI method 13409 for infrequent production, or small batch guidelines. The sterilization will be in the range 25Kgy to 40Kgy, and be performed by the Sterilizer, Sterigenics, Inc. at its facility in Schaumburg, Illinois.

5. Characteristics of Device

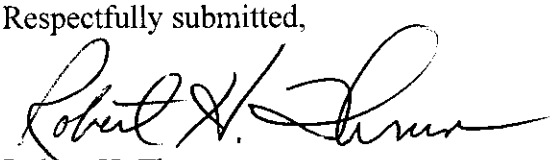
Substantially, the materials and components for this device are the same as those used in device K982013 with the exception of the two metal arms and the stainless steel pusher rod.

6. Safety Information

Safety and effectiveness information will be provided to interested parties.

Do not hesitate to contact me at 630/543-9124 if you have any questions about this Summary.

Respectfully submitted,



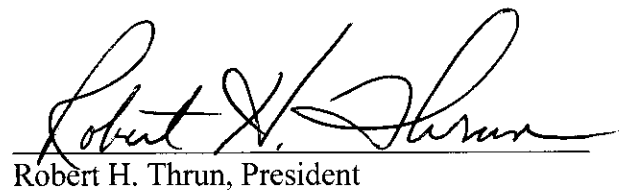
Robert H. Thrun
President

RHT:j
Enclosures

510 (k) STATEMENT

I certify that, in my capacity as President of Anchor Products Company, I will make available all information included in this premarket notification on safety and effectiveness within thirty days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Dated: June 1, 2006



Robert H. Thrun, President

(b)(4)Trade Secret Process - Design Drawing

Exhibit B

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-100 XL	xxxxx	xxxxxxxxxxxx

Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Della Hammond

Subject: 510(k) Number K061555/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.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

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

☐ The required certification and summary for class III devices

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☑ NO Material of Biological Origin ☐ 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):

CLASS II
GCJ
876.1500 - Endoscope & accessories

Review: [signature] GSDB 8/31/06
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] [signature] 8/31/06
(Division Director) (Date)

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Revised:4/2/03

Internal Administrative Form

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

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

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 061555

Reviewer: Della Hammond

Division/Branch: DGRND/GSDB

Device Name: Anchor Laparoscopic Tissue Retrieval Bag

Product To Which Compared (510(K) Number If Known): K982073

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

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

510K MEMORANDUM

Division of General and Restorative Devices
General Surgical Devices Branch, HFZ-410

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

MEMORANDUM
K061555

Date: August 28, 2006

To: The Record

From: Della Hammond, MPH, Microbiologist, General Surgical Devices Branch, DGRND

Company: Anchor Products Company
Contact: Robert H. Thurn
Phone: 630-543-9124 Fax: 630-543-9131
Email: www.anchorsurgical.com
Device: Anchor Laparoscopic Tissue Retrieval Device
Predicate: Anchor Laparoscopic Tissue Retrieval Device (original)
Dated: June 1, 2006
Date Recd: June 5, 2006

PRODUCT SUMMARY

The following provides the identification and classification of the proposed device:

Proprietary Name:	Anchor Laparoscopic Tissue Retrieval Device
Device/Product Name:	Laparoscopic Specimen Bag
Regulation Name:	Endoscope and Accessories
Regulation Number:	876.1500
Device Class:	II
Product Code:	GCJ
510(k)	K061555
Predicate Number(s):	**K982073** ***SE**

INDICATION FOR USE

The Anchor Laparoscopic Tissue Retrieval System is intended for use by surgeons in laparoscopic and endoscopic surgical procedures when removal of tissue or debris from the abdominal cavity is desired.

Reason for This Submission

The proposed Anchor Laparoscopic Tissue Retrieval System is being introduced to incorporate minor modifications in the retrieval system. (b)(4)Trade Secret Process [redacted]

SUMMARY

The firm has submitted an adequate 1) 510K Statement, 2) Indication for Use, 3) Device Description, 4) Engineering/Technical Drawing, 5) Truthful and Accurate Statement, and 7) Comparison Chart.

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(b)(4)Trade Secret Process

PREDICATE DEVICE

The firm is claiming substantial equivalence to their original device, K982013, the Anchor Laparoscopic Tissue Retrieval System. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

Differences

The proposed Anchor Laparoscopic Tissue Retrieval System is being introduced to incorporate minor modifications in the retrieval system. (b)(4)Trade Secret Process

DEVICE DESCRIPTION

The proposed device is a redesigned, disposable, polyamide nylon pouch that is used with an introducer tube and is defined to fit into a previously placed trocar entry port and inserted into the body cavity during laparoscopic and endoscopic surgical procedures when removal of tissue or debris from the abdominal cavity is desired. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

MATERIALS

(b)(4)Trade Secret Process

12

(b)(4)Trade Secret Process

Biocompatibility Data (see S1 dated August 4, 2006)

(b)(4)Trade Secret Process

TECHNICAL [CQ7]

(b)(4)Trade Secret Process

Performance Testing

(b)(4)Trade Secret Process

STERILITY

The product will be sold as a sterile product.

The device is sterilized by (b)(4)Trade Secret Process

Sterilization process

(b)(4)Trade Secret Process

PACKAGING

Tyvek pouch

LABELING

The firm has provided adequate labeling as Exhibit B and Supplement of this submission.

COMMUNICATIONS LOG:

The firm was contacted via email on 07/17/06 to provide the following information:

- New materials
- IFU
- T&A Statement
- Predicate Labeling
- Biocompatibility testing
- Performance testing
- Device description

07/19/06: Firm sent email to inform me that they are in the process of providing the information requested.

13

08/16/06: Requested information received. (b)(4)Trade Secret Process [redacted]

08/17/06: This reviewer sent an email to the firm to request data for (b)(4)Trade Secret [redacted]
08/24/06: The firm sent an email of a (b)(4)Trade Secret Process [redacted].
This reviewer requested via email that the firm provide the data for these tests.

08/25/06: Requested data received.

RECOMMENDATION: SE, K061555
The proposed Anchor Laparoscopic Tissue Retrieval System shares similar features and functions with the corresponding predicate device with regard to function, indications, materials, sterilization, and labeling. The similarities and differences are comparable. My review of the imaged predicate did not reveal any significant characteristic differences. Therefore, I find the proposed device to be substantially equivalent to the predicate. There are no new safety and effectiveness issues.

_____ 8/31/06 _____ /X/Concur
Branch Chief, Date / / Do Not Concur
Division of General, Restorative and Neurological Devices
General Surgical Devices Branch

_____ / /Concur
Deputy Division Director Date / / Do Not Concur
Division of General, Restorative and Neurological Devices

_____ / /Concur
Division Director Date / / Do Not Concur
Division of General, Restorative and Neurological Devices

Comments:

Hammond, Della

Dear Ms. Hammond,
Sorry for any confusion. We weren't sure how much detail you wanted. These tests were all completed in July of this year. Please let me know if you have any questions.
Regards, Robert H. Thrun

From: Hammond, Della [mailto:della.hammond@fda.hhs.gov]
Sent: Wednesday, August 23, 2006 6:39 AM
To: 'Robert Thrun'
Subject: RE: Anchor tissue retrieval system K061555

Where is the data?

Della Hammond, Lead Reviewer
General Surgical Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation
US Food and Drug Administration
Center for Devices and Radiological Health
Telephone: 301-594-3091
Facsimile: 301-827-4350
dah@cdrh.fda.gov
OR: della.hammond@fda.hhs.gov

From: Robert Thrun [mailto:Rthrun@anchorsurgical.com]
Sent: Tuesday, August 22, 2006 4:52 PM
To: Hammond, Della
Subject: RE: Anchor tissue retrieval system K061555

Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch
Material Puncture/Burst Test Results

(b)(4)Trade Secret Process

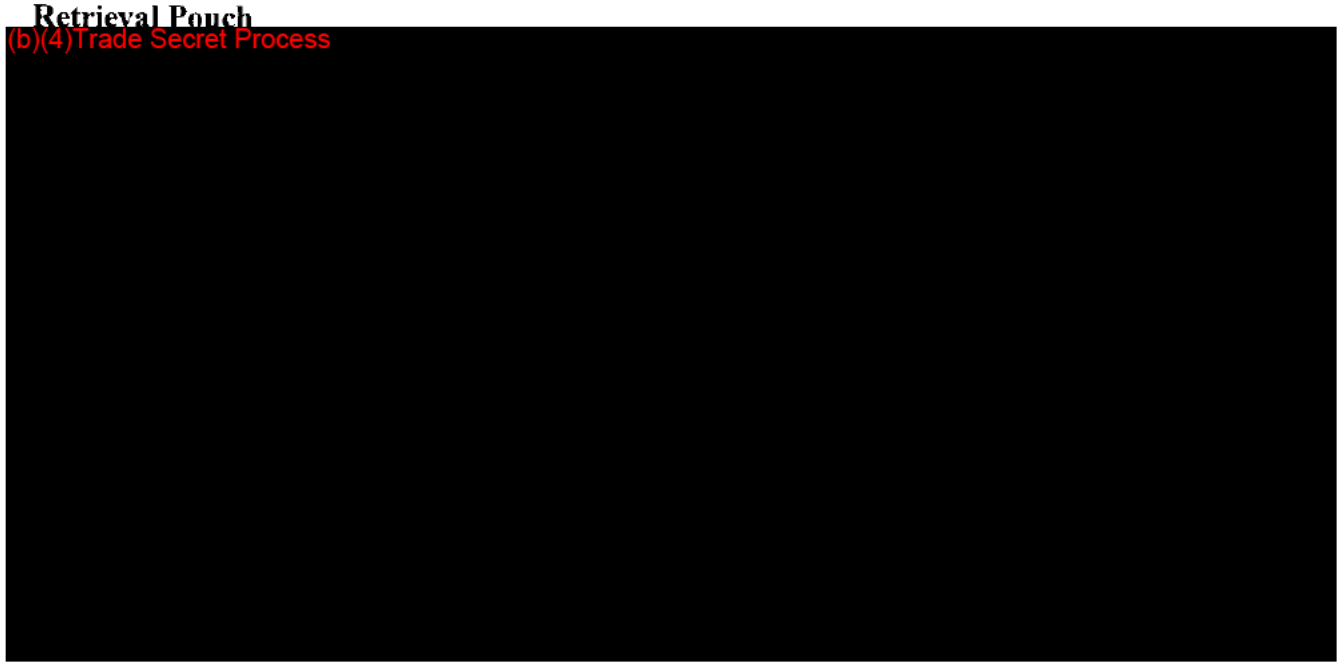
Manufacture lot #	(b)(4)Trade Secret Process	Required standard 12 lbs
Lot # 1		Pass
Lot # 2		Pass
Lot # 3		Pass
Lot # 4		Pass
Lot # 5		Pass
Lot # 6		Pass
Lot # 7		Pass
Lot # 8		Pass
Lot # 9		Pass
Lot # 10		Pass
Lot # 11		Pass
Lot # 12		Pass
Lot # 13		Pass
Lot # 14		Pass
Lot # 15		Pass
Lot # 16		Pass
Lot # 17		Pass
Lot # 18		Pass
Lot # 19		Pass
Lot # 20		Pass
Lot # 21		Pass

(b)(4)Trade Secret Process

Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch

(b)(4)Trade Secret Process



Material Lot number(b)

Roll # 1	Test 1	Test 2	Test 3	Passed
Roll # 2	Test 1	Test 2	Test 3	Passed
Roll # 3	Test 1	Test 2	Test 3	Passed
Roll # 4	Test 1	Test 2	Test 3	Passed
Roll # 5	Test 1	Test 2	Test 3	Passed
Roll # 6	Test 1	Test 2	Test 3	Passed
Roll # 7	Test 1	Test 2	Test 3	Passed
Roll # 8	Test 1	Test 2	Test 3	Passed

(b)(4)Trade Secret Process

Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch

(b)(4)Trade Secret Process [redacted]

Lot number	[redacted]
Set up station # 1	
Set up station #2	
Lot #1	
Test station # 1	
Test station # 2	
Lot # 2	
Test station #1	
Test station # 2	
Lot # 3	
Test station #1	
Test station #2	
Lot # 4	
Test station #1	
Test station #2	
Lot #5	
Test station #1	
Test station #2	

(b)(4)Trade Secret Process

Lot # 6	(b)(4)Trade Secret Process
Test station #1	
Test station #2	
Lot # 7	
Test station #1	
Test station #2	
Lot # 8	
Test station #1	
Test station #2	
Lot # 9	
Test station #1	
Test station #2	
Lot # 10	
Test station #1	
Test station #2	
Lot # 11	
Test station #1	
Test station #2	
Lot # 12	
Test station #1	
Test station #2	
Lot # 13	
Test station #1	
Test station #2	
Lot # 14	
Test station #1	
Test station #2	
Lot # 15	
Test station #1	
Test station #2	

Lot # 16
Test station #1
Test station #2
Lot # 17
Test station #1
Test station #2
Lot # 18
Test station #1
Test station #2
Lot # 19
Test station #1
Test station #2
Lot # 20
Test station #1
Test station #2
Lot # 21
Test station #1
Test station #2

(b)(4)Trade Secret Process

(b)(4) Trade Secret Process

3

Hammond, Della

Dear Ms. Hammond,
In response to your request, I have included three attachments. Please let me know if you need more details or have any other questions.
Regards, Robert H. Thrun

From: Hammond, Della [mailto:della.hammond@fda.hhs.gov]
Sent: Thursday, August 17, 2006 9:08 AM
To: 'Robert Thrun'
Subject: RE: Anchor tissue retrieval system K061555

Dear Mr. Thrun:

I have reviewed the additional information you have provided for the device referenced above. I cannot determine the device to be substantially equivalent to a legally marketed device based solely on the information you have provided. To complete the review, please provide the following information:

(b)(4)Trade Secret Process

[redacted]

Please provide the data for these tests.

If you wish, you may send this information via email or to the fax number provided below.

Thank you,

Della Hammond, Lead Reviewer
General Surgical Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation
US Food and Drug Administration
Center for Devices and Radiological Health
Telephone: 301-594-3091
Facsimile: 301-827-4350
dah@cdrh.fda.gov
NEW: della.hammond@fda.hhs.gov

From: Robert Thrun [mailto:Rthrun@anchorsurgical.com]
Sent: Tuesday, August 08, 2006 1:10 PM
To: Hammond, Della
Subject: Anchor tissue retrieval system K061555

Hello Ms. Hammond,

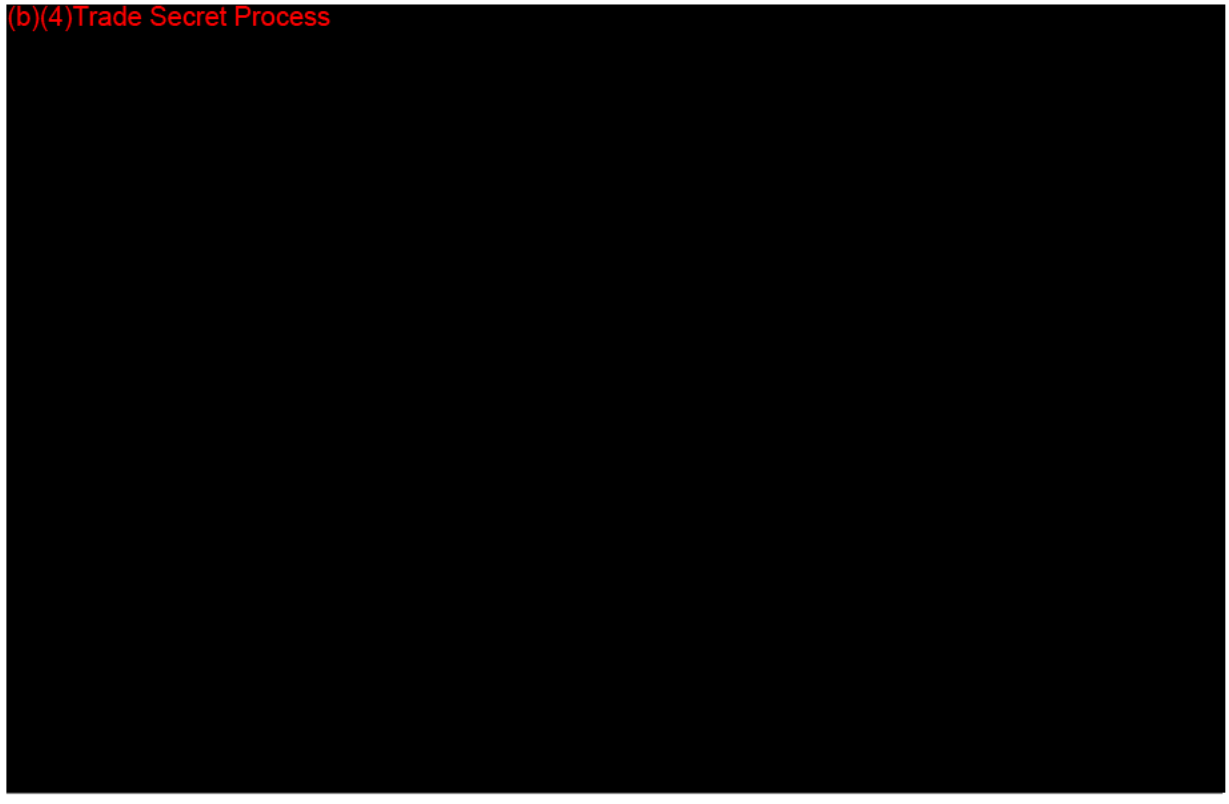
Yesterday I sent a package to you via Fed Ex, which you should receive today. We had trouble converting everything to a format we could e-mail and were also concerned that some pages might not come through clearly by fax. I hope this is ok. Please let me know if there is anything more you need at this time.

Sincerely, Robert H. Thrun

Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch

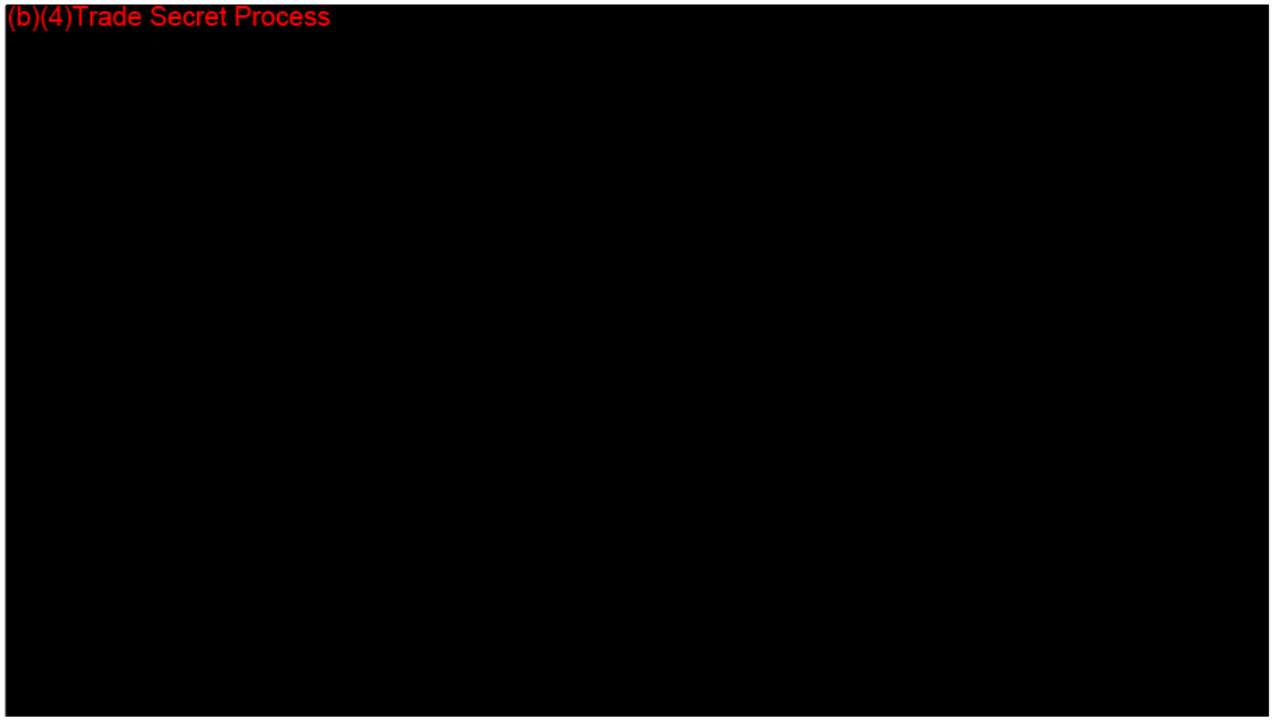
(b)(4)Trade Secret Process



Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch

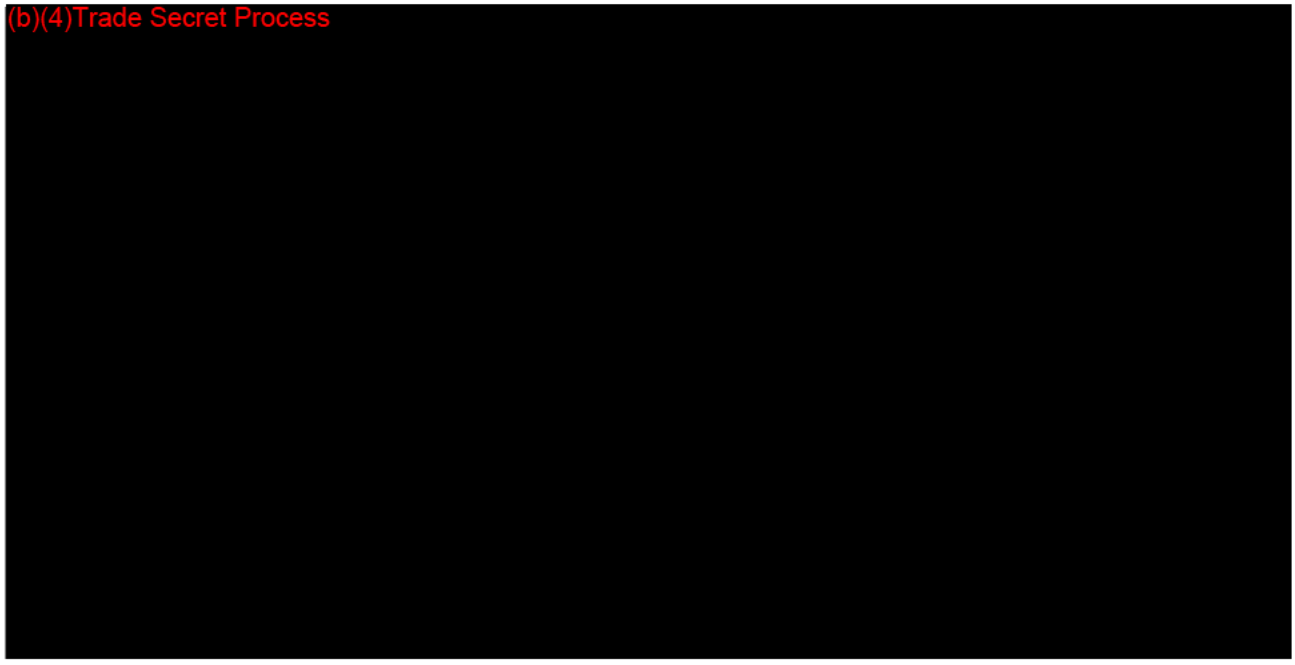
(b)(4)Trade Secret Process



Anchor Products Company
Tissue Retrieval System
510K Submission # K061555

Retrieval Pouch

(b)(4)Trade Secret Process



(1)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Della Hammond

Subject: 510(k) Number K061555

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☐ Enclosed
☐ A 510(k) summary OR ☐ A 510(k) statement
☐ The required certification and summary for class III devices
☐ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ 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 day

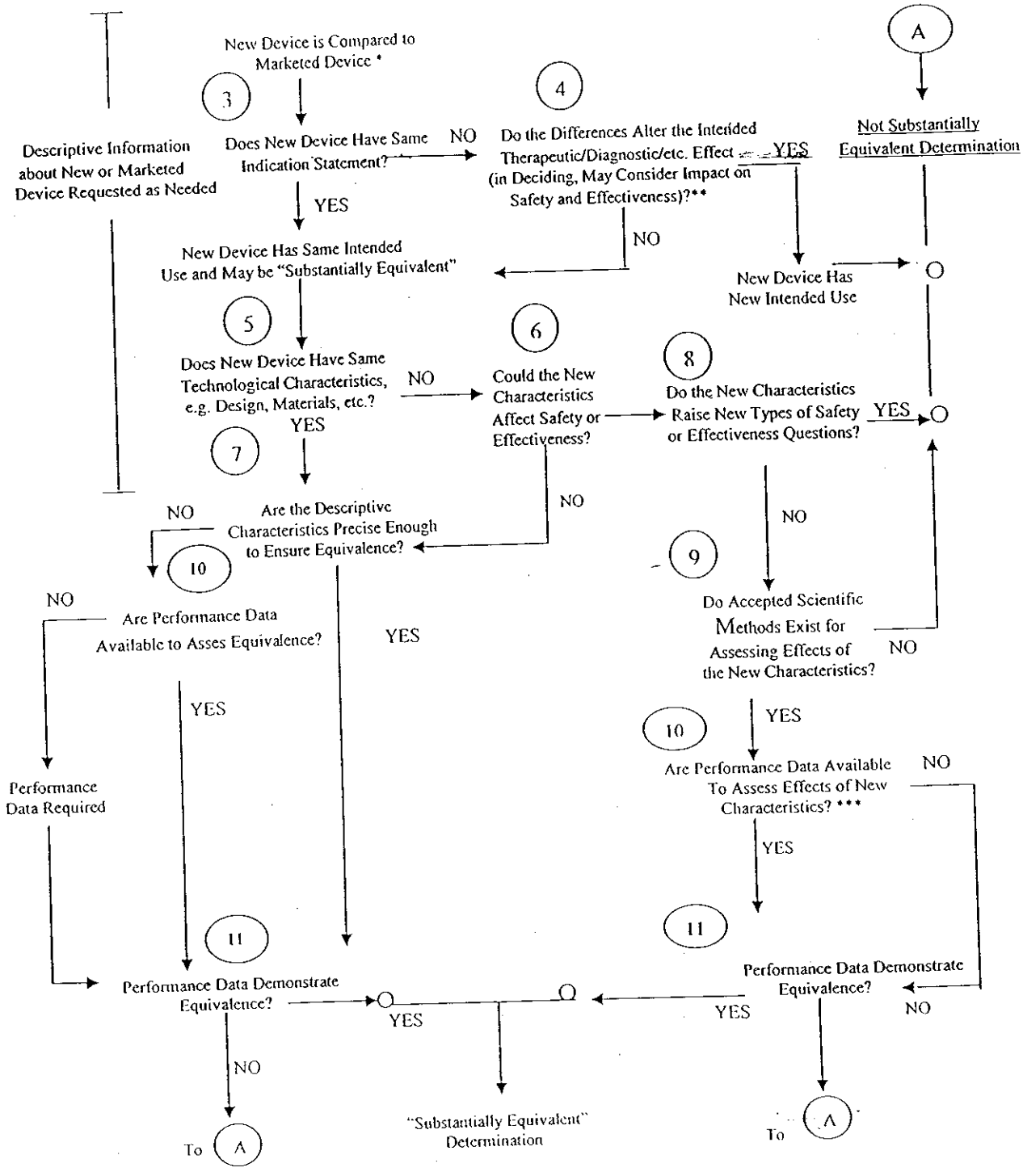
Predicate Product Code with class: Additional Product Code(s) with panel (optional):

Review: Neil R Ogden GSDB 7/26/06
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

Revised:4/2/03

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.

Internal Administrative Form

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

(4)

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

510(k) Number: _____

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

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

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

* - 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:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

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:_____

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

(8)

REVISED:3/14/95

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

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

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

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

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

1. Intended Use:

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

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

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Division of General and Restorative Devices
General Surgical Devices Branch, HFZ-410

Food and Drug Administration
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

MEMORANDUM
K061555

Date: July 26, 2006

To: The Record

From: Della Hammond, MPH, Microbiologist, General Surgical Devices Branch, DGRND

Company: Anchor Products Company
Contact: Robert H. Thurn
Phone: 630-543-9124 Fax: 630-543-9131
Email: www.anchorsurgical.com
Device: Anchor Laparoscopic Tissue Retrieval Device
Predicate: Anchor Laparoscopic Tissue Retrieval Device (original)
Dated: June 1, 2006
Date Recd: June 5, 2006

PRODUCT SUMMARY

The following provides the identification and classification of the proposed device:

Proprietary Name:	Anchor Laparoscopic Tissue Retrieval Device
Device/Product Name:	Laparoscopic Specimen Bag
Regulation Name:	Endoscope and Accessories
Regulation Number:	876.1500
Device Class:	II
Product Code:	GCJ
510(k)	K061555
Predicate Number(s):	**K982073** ***HOLD**

INDICATION FOR USE

The Anchor Laparoscopic Tissue Retrieval System is intended for use by surgeons in laparoscopic and endoscopic surgical procedures when removal of tissue or debris from the abdominal cavity is desired.

Reason for This Submission

The proposed Anchor Laparoscopic Tissue Retrieval System is being introduced to incorporate minor modifications in the retrieval system. (b)(4)Trade Secret Process [redacted].

SUMMARY

The firm has submitted an adequate 1) 510K Statement, 2) Indication for Use, 3) Device Description, 4) Engineering/Technical Drawing, 5) Truthful and Accurate Statement, and 7) Comparison Chart.

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(b)(4)Trade Secret Process

PREDICATE DEVICE

The firm is claiming substantial equivalence to their original device, K982013, the Anchor Laparoscopic Tissue Retrieval System. (b)(4)Trade Secret Process

Differences

The proposed Anchor Laparoscopic Tissue Retrieval System is being introduced to incorporate minor modifications in the retrieval system. (b)(4)Trade Secret Process

DEVICE DESCRIPTION

The proposed device is a redesigned, disposable, polyamide nylon pouch that is used with an introducer tube and is defined to fit into a previously placed trocar entry port and inserted into the body cavity during laparoscopic and endoscopic surgical procedures when removal of tissue or debris from the abdominal cavity is desired. (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

MATERIALS

Your submission states the material and components for the device are the same as those in the predicate device with the exception of (b)(4)Trade Secret Process
(b)(4)Trade Secret Process

93

[redacted] (b)(4)T

Biocompatibility Data *(in the predicate?)*
(b)(4)Trade Secret Process [redacted]

TECHNICAL [CQ7] *requested*

Performance Testing

STERILITY
The product will be sold as a sterile product.

The device is sterilized by [redacted] (b)(4)Trade Secret P

Sterilization process
(b)(4)Trade Secret Process [redacted]

PACKAGING
Tyvek pouches –*how many per box (Requested)*

LABELING
The firm has provided adequate labeling as Exhibit B of this submission.

COMMUNICATIONS LOG:
The firm was contacted via email on 07/17/06 to provide the following information:

- New materials
- IFU
- T&A Statement
- Predicate Labeling
- Biocompatibility testing
- Performance testing
- Device description

07/19/06: Firm sent email to inform me that they are in the process of providing the information requested.

RECOMMENDATION: SE, K061555
No information has been received by the firm to date. A determination of SE cannot be made until the sponsor has provided adequate responses to the requested information. Therefore, this application will be placed on HOLD effective 07/26/06 until the requested information is received.

Neil 7/26/06 /✓/ Concur
Branch Chief, Date / / Do Not Concur
Division of General, Restorative and Neurological Devices
General Surgical Devices Branch

94

_____ / /Concur
Deputy Division Director Date / / Do Not Concur
Division of General, Restorative and Neurological Devices

_____ / /Concur
Division Director Date / / Do Not Concur
Division of General, Restorative and Neurological Devices

Comments:

Hammond, Della

From: Robert Thrun [Rthrun@anchorsurgical.com]
Sent: Wednesday, July 19, 2006 5:27 PM
To: Hammond, Della
Subject: RE: Anchor Tissue Retrieval - K061555

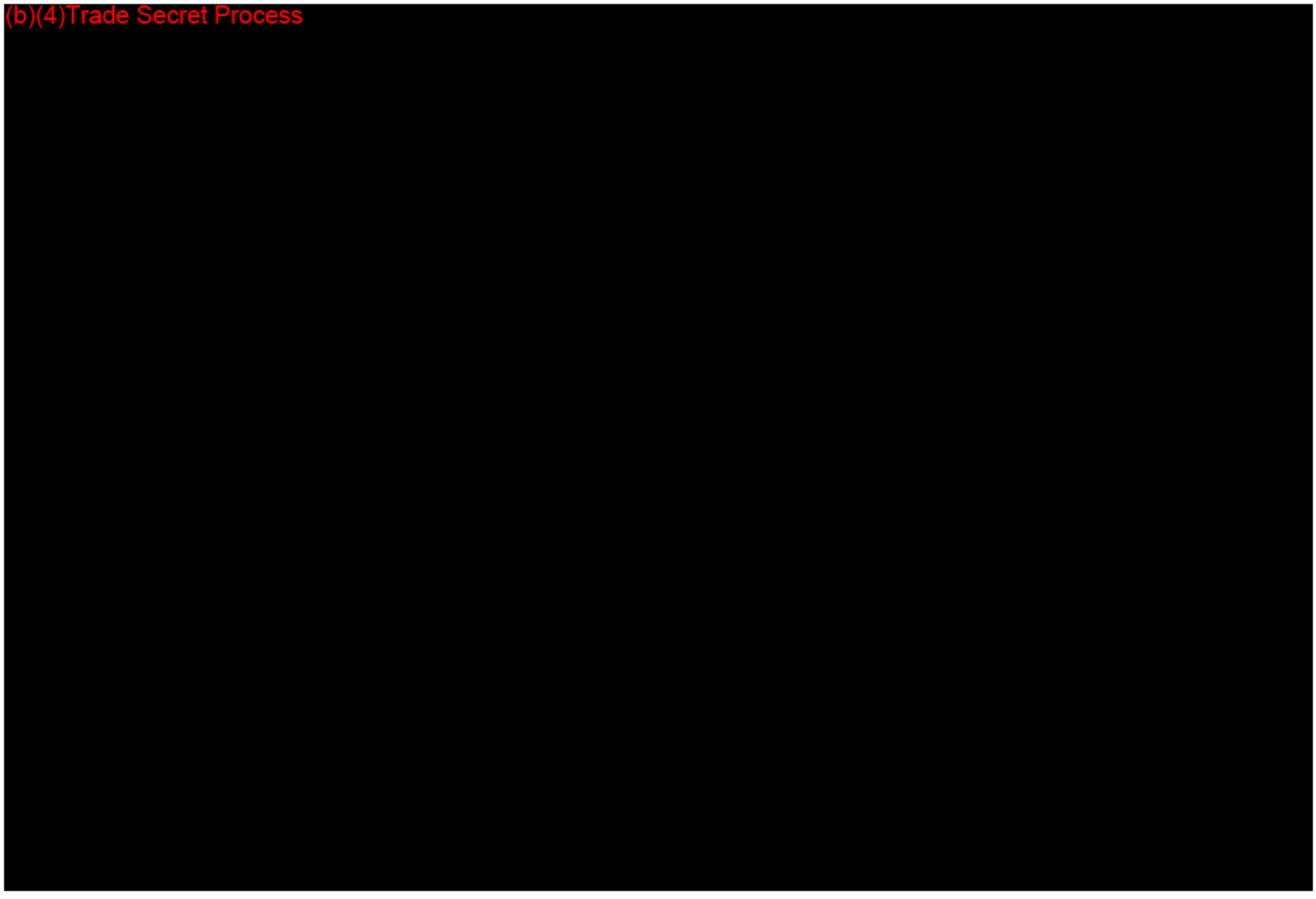
Dear Ms. Hammond,
We are reviewing your questions and are in the process of answering all. I would like to ask you to resend the attachment which I believe is meant to be the appropriate form for providing the "indications for use statement". The attachment we opened only showed the FDA centennial insignia. Thank you for your help.
Sincerely, Robert H. Thrun

From: Hammond, Della [mailto:della.hammond@fda.hhs.gov]
Sent: Monday, July 17, 2006 1:55 PM
To: 'rthrun@anchorsurgical.com'
Subject: Anchor Tissue Retrieval - K061555

Dear Mr. Thrun,

I have reviewed your notification of intent to market the device referenced above; however, I cannot determine the device to be substantially equivalent to a legally marketed device based solely on the information you have provided. To complete the review, please provide the following information:

(b)(4)Trade Secret Process



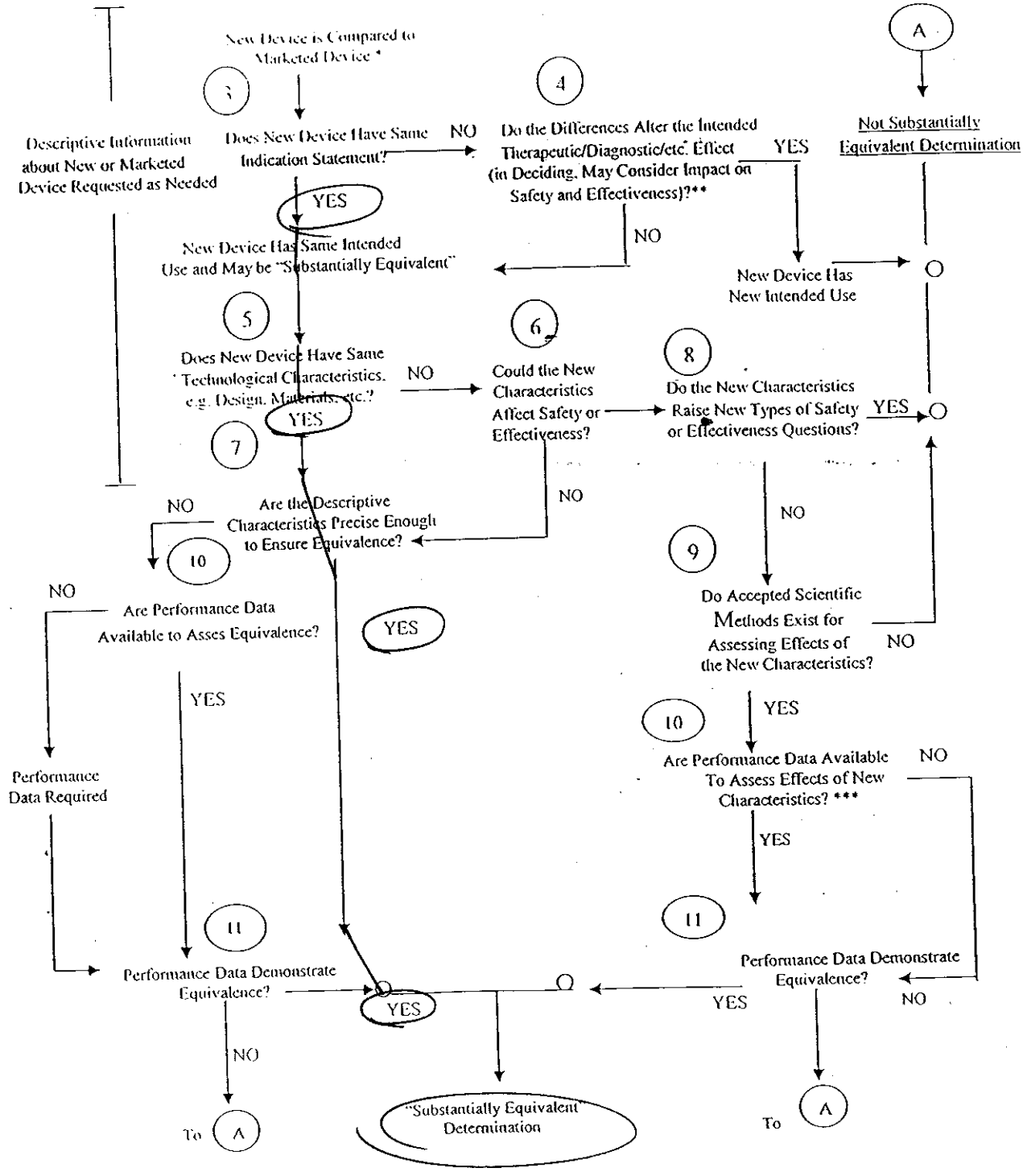
(b)(4)Trade Secret Process

If you wish, you may email your response, or fax this information to the fax number given below.

Thank you,

Della Hammond, Lead Reviewer
General Surgical Devices Branch
Division of General and Restorative Devices
Office of Device Evaluation
US Food and Drug Administration
Center for Devices and Radiological Health
Telephone: 301-594-3091
Facsimile: 301-827-4350
dah@cdrh.fda.gov
NEW: della.hammond@fda.hhs.gov

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

August 17, 2006

ANCHOR PRODUCTS CO.
52 OFFICIAL RD.
ADDISON, IL 60101
ATTN: ROBERT H. THRUN

510(k) Number: K061555
Product: ANCHOR LAPARSCOPIC TISSUE RETIEVAL SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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 in 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

K061555/S1

ANCHOR PRODUCTS COMPANY
52 Official Road, Addison, IL 60101-4589
Telephone 630/543-9124
800/323-5134 www.anchorsurgical.com
FAX 630/543-9131 Email: info@anchorsurgical.com

August 4, 2006

Ms.Della Hammond, Lead Reviewer
General Surgical Devices Branch
Division of General and Restorative Devices
Office of Drug Evaluation
US Food and Drug Administration

Re: Anchor Tissue retrieval System - K061555

Dear Ms. Hammond:

I am submitting with this letter an Indications for Use Statement, T & A Statement, Biocompatibility Testing with previous results listed as Exhibit A, Performance Testing, Predicate Labeling, Device Materials, Device Description, Comparison between old and new products, a set of Product Labels, and Exhibit B, instructions for use.

I trust that this information will permit you to complete your review, however, if you have any questions or comments about this information, do not hesitate to call me.

Respectfully Submitted,

Robert H. Thrun, President

RHT:EF
encl.

K38

Indications for Use

510(k) Number (if known): K061555

Device Name: Anchor Tissue Retrieval System

Indications For Use:

The Anchor Tissue retrieval system is a sterile disposable pouch used with a dedicated introducer for the encapture and removal of an organ or tissue from the body cavity during laparoscopic surgery.

Prescription Use __X_____ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

August 4, 2006,

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As required by 21 CFR 807.87(i))

I certify that, in my capacity as the President of Anchor Products company, Inc., 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.

Robert H. Thrun

August 4, 2006

K061555
[Premarket Notification (510K) K061555]

Anchor Products Company
510K number K061555

BIOCOMPATIBILITY TESTING

(b)(4)Trade Secret Process

TESTING ATTACHMENTS

EXHIBIT A

1. (b) (4)Trade Secret REPORT NUMBER X8B006G
2. (b) (4)Trade REPORT NUMBER X8B007G
3. (b) (4)Trade Secret REPORT NUMBER V8B007G

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

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(b)(4)Trade Secret Process - Testing Report

Anchor Products Company
Anchor Tissue Retrieval Pouch
510 K Submission K061555

Predicated Labeling

Similarity between commercially available products.

Company name	Pouch material specification	Type of delivery system	Type of introducer rod	Draw string	Introducer tube	Intended use	Method of use
[redacted]							

* With tail to aid removal.

Anchor Products Company
510K – K061555
Bill of Materials

Device Materials

Part number	Description	Material
(b)(4)Trade Secret Process - Testing Report		

Anchor Products Company
510K – K061555
Bill of Materials

Device Materials

Part number	Description	Material
(b)(4)Trade Secret Process - Testing Report		

Anchor Products Company
510K – K061555
Bill of Materials

Device Materials

Part number	Description	Material
(b)(4)Trade Secret Process - Testing Report		

Anchor Products Company
510K – K061555
Bill of Materials

Device Materials

Part number	Description	Material
(b)(4)Trade Secret Process - Testing Report		

Anchor Products Company
510K – K061555
Bill of Materials

Device Materials

Part number	Description	Material
(b)(4)Trade Secret Process - Testing Report		

Anchor Products Company
Anchor Tissue retrieval System
510 K submission K061555

DEVICE DESCRIPTION

The Anchor tissue retrieval system is a sterile, disposable rip-stop nylon pouch coated with polyurethane, to be available in five (5) pouch sizes, with an introducer tube.

The pouch is suspended from two nitinol arms, which are connected to a stainless steel pusher rod. The pouch and stainless steel pusher rod are inserted into a polycarbonate introducer tube as shown in the illustration marked Exhibit B. The introducer tube containing the pouch then is inserted into the body cavity down an entry port, under direct visual control.

The pouch opens when the nitinol arms extend, after the surgeon pushes on the stainless steel pusher as illustrated. After the sample or organ is placed into the pouch, the stainless steel pusher and arms are removed and the mouth of the pouch is closed with the drawstring. The pouch is then removed through the entry port incision in the abdomen.

Anchor intends to produce five different pouch sizes depending on market demand with approximate capacities of 100ml, 150ml, 220ml, and 700ml and 850ml.

The three smaller sizes, 100ml, 150ml, and 220ml fit down a 10mm entry port and the two larger sizes fit down a 15mm entry port. The entry ports are not supplied.

Anchor Products Company

Comparison between the Anchor Tissue Retrieval System set forth in 510(K) #982073 ("OLD DEVICE") and the redesigned Anchor Tissue retrieval System set forth in 510(K) #061555 ("NEW DEVICE").

(b)(4)Trade Secret Process


(b)(4)Trade Secret Process

Product label

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-065 XL	**XXXXX**	**XXXXXXXXXXXX**

Approximate capacity 100ml

Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free
RX only

Product label

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-085 XL	XXXXX	XXXXXXXXXXXX

Approximate capacity 150ml

Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free
RX only

Product label

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-100 XL	XXXXX	XXXXXXXXXXXX

Approximate capacity 220ml

Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free
RX only

Product label

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-180 XL	XXXXX	XXXXXXXXXXXX

Approximate capacity 700ml

Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free
RX only

Product label

anchor
Tissue Retrieval System
Sterile Disposable

Code #	Lot #	Expiration Date
TRS-200 XL	**XXXXX**	**XXXXXXXXXXXX**

Approximate capacity 850ml

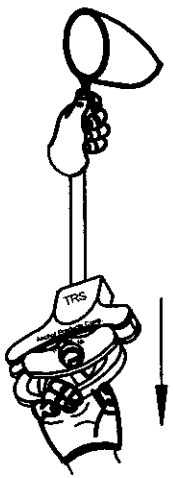
Anchor Products Company
52 Official Road
Addison, IL 60101
USA

Phone 630 543 9124
Toll Free 800 323 5134
Fax 630 543 9131
anchorsurgical.com

Sterilized by Irradiation
Sterility guaranteed unless package is opened or damaged
Do Not Resterilize
Single Patient Use- See Instructions For Use
Product is Latex Free
RX only

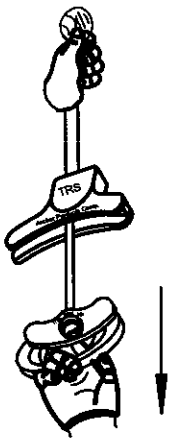
Exhibit B Instructions for Use

(1)



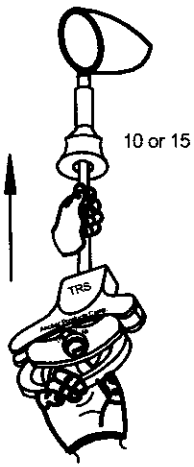
Pull pouch into introducer tube.

(2)



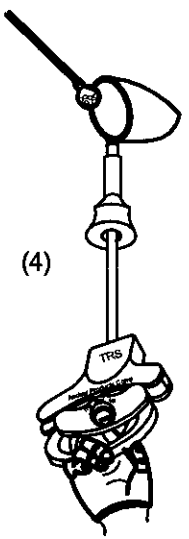
Squeeze excess air out
of retrieval pouch as it
enters introducer tube.
Pouch is now ready for deployment.

(3)



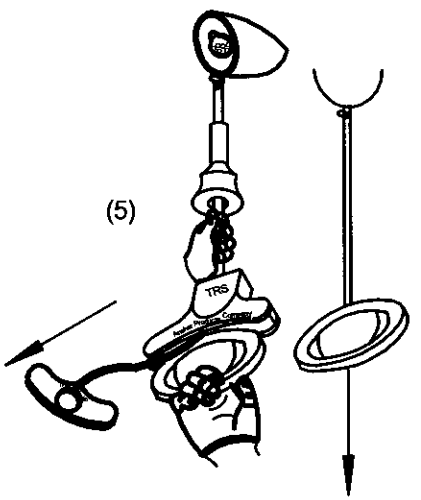
Deploy device down in-place entry port,
retrieval pouch opens automatically

(4)



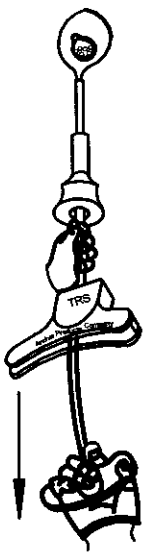
Using grasping instrument place
captured tissue or organ into pouch

(5)



Remove drawstring holder prior
to removing pusher rod assembly

(6)



Pull draw-string to close pouch mouth.
Remove introducer tube, entry
port and at the same time pull mouth
of pouch to outside of abdomen.