DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 11, 2014

Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K050516
Trade/Device Name: T-Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OTN
Dated (Date on orig SE ltr): November 28, 2005
Received (Date on orig SE ltr): December 19, 2005

Dear Marla Kengen:

This letter corrects our substantially equivalent letter of February 3, 2006.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known) K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Herbert P. Lerner -S
2014.03.27 13:33:36 -04'00'

Prescription Use__x OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

HERNIAMESH SRL
Sede legale Via Fratelli Melga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 – C. F. 02245180613 - N. iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

PRSD 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1/13/2014

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K050516/A003

To: Division Director: SU/DSD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

__✓__ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: Sharon Andrews

Date: 3/19/14

K050516/A3

Chivasso, February 26th, 2014

FDA
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K050516/A003
T-Sling
510(k) number: K050516
Letter from CDRH received on: December 9, 2013

This add–to-file letter is in response to the letter we received from CDRH accepting our request of removing reference to vaginal prolapse repair from the Indication for Use statement of 510(k) K050516.

The add-to-file letter should be reviewed by the Office of Device Evaluation (ODE), Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Obstretics and Gynecology Devices Branch (OGDE).

Here attached:

- 510(k) Summary and Indication for Use Form
- IFU

The eCopy is an exact duplicate of the paper copy

Sincerely yours,

Eng. Roberta Lamberti
QARA and R&D Manager
Herniamesh S.r.l.

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 – C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

K050516 | A003

Chivasso, December 20th, 2013

FDA
k.a. Sharon M. Andrewws
Biomedical Engineer, DRUG/OGDB
10903 New Hampshire Avenue
WO66, Room G110
Silver Spring, MD 20993.

Re: PS130047
T-Sling
510(k) number: K050516
Letter from CDRH received on: December 9, 2013

This add–to-file letter is in response to the letter we received from CDRH accepting our request of removing reference to vaginal prolapse repair from the Indication for Use statement of 510(k) K050516.

The add-to-file letter should be reviewed by the Office of Device Evaluation (ODE), Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Obstretics and Gynecology Devices Branch (OGDE).

Here attached:

- Indication for Use Form
- 510(k) Summary
- Labelling

Sincerely yours,

Eng. Roberta Lamberti
QARA and R&D Manager
Herniamesh S.r.l.

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
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Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

K050516/B A3

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: Herniamesh SRL
Via Fratelli Meliga 1/C
Chivasso, Italy
Tel +39 011 9196236 Fax + 011 550 40 85

Contact: Lorena Trabucco
540 MUTTONTOWN EASTWOODS ROAD
Syosset, NY 11791
Tel 516 987-9364 – 516 584 6818
e-mail: lorenat63@aol.com

Date Prepared: December 20th, 2013

Classification: Polymeric Surgical Mesh (product code FTL) Class II device per 21 CFR 87.8.330

Common Name: Polymeric Surgical Mesh

Proprietary Name: T-Sling

Predicate Devices: **K020652** T-Sling (Herniamesh)
K010035 IVS Tunneller (Tyco Healthcare)
K012628 TVT (Ethicon)

Device Description: The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).

Intended Use: T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Coloplast

T-Sling

Fold

English

T-Sling

REF 519400

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

Description
Non-absorbable knitted monofilament polypropylene mesh provided with protective sheaths and pre-assembled sutures.

Indications
T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Sterilization
The **T-Sling** is sterilized with ethylene oxide.

Packaging
Each **T-Sling** sling is packed in a double blister, both shell are sealed by a Tyvek® film. Only the inner blister is sterile.

Storage
This product must be stored at room temperature, in a clean dry place. Do not expose the product to direct sunlight, humid environments or extreme temperatures.

Adverse Reactions
Potential adverse reactions are similar to those associated with other surgically implanted materials or devices. This may include infection, acute and chronic inflammation with possible functional alteration of the organs involved, adhesions, fistula formation, erosion and rejection. Perforations or laceration of blood vessels, nerves, bladder, bowel and uterus may occur during passage of needles and might require open surgical repair.

Manufactured by:
Herniamesh S.r.l.
Via Fratelli Melga 1/C
10034 Chivasso (To) - Italia

Distributor:
Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

Fold

Contraindications and Warnings ⚠

1.**T-Sling** will not stretch significantly and therefore this product should not be used in patients with potential growth and in women who are planning future pregnancies.

2.As with any suspension procedure, this product should not be used on patients who are taking anti-coagulants or anti-aggregating drugs, non-steroidal anti-inflammatory agents, or in patients that have any blood disease with hemorrhagic tendencies.

3.The **T-Sling** must not be used in contaminated wounds; in presence of infections the removal of the sling may be required.

4.The **T-Sling** must not be placed in contact with the bowel or other viscera.

5.Excessive tension on the sling can cause obstruction of the urethra or of the lower urinary tract that, even if transitory, could result in postoperative urinary retention (anterior approach).

6.Surgeons who intend to use **T-Sling** must have experience of the different surgical techniques regarding the vaginal vault and bladder neck suspensions.

7.As in all suspension procedures, retropubic haemorrhaging may occur if the transvaginal approach is used. It is therefore necessary to monitor all the patient's symptoms relating to this phenomenon before her release from the hospital.

8.After positioning the sling with the anterior approach (transvaginal retro pubic), a cystoscopy must be performed in order to confirm the integrity of the bladder to locate a possible perforation. In the transobturator and posterior approach cystoscopy is at the discretion of the surgeon.

9.The vaginal vault suspension by posterior approach can be performed simultaneously with cystocele, rectocele and enterocele repair.

10.Do not implant using staples or clips this may cause mechanic al damage to the sling.

11.Do not use in patients that have known allergies to polypropylene.

12.The **T-Sling** is a single-use product. Do not resterilize

13.Do not use the product if the Tyvek® pouch package has been opened or damaged, or after expiration date.

Product Traceability
Product traceability labels are included in every package and are used to identify type and lot number of the prosthesis. The label should be applied to the patient's medical records in order to clearly identify the product that was implanted.

Product Evaluation
Please contact Product Evaluations Department, Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free 800-338-7908.

Product Order Information or Returned Goods Authorization
Please call Customer Service Department, Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free (800) 258-3476.

References
Literature references are available upon request from:
Coloplast Customer Service
1601 West River Road North
Minneapolis, MN 55411 USA
Toll-free telephone (800) 258-3476

Sterilized Using Ethylene Oxide
Caution: Consult Accompanying Documents
Do Not Use If Package Is Damaged
Do Not Resterilize
Do Not Reuse

Indications for Use Form

510(k) Number (if known) K050516

Device Name: T-Sling

Indications For Use:

T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

_____ _____ _____ _____ _____ _____

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use__x OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. - P.I. 02791540616 - C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
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Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: Herniamesh SRL
Via Fratelli Meliga 1/C
Chivasso, Italy
Tel +39 011 9196236 Fax + 011 550 40 85

Contact: Lorena Trabucco
540 MUTTONTOWN EASTWOODS ROAD
Syosset, NY 11791
Tel 516 987-9364 – 516 584 6818
e-mail: lorenat63@aol.com

Date Prepared: December 20th, 2013

Classification: Polymeric Surgical Mesh (product code FTL) Class II device per 21 CFR 87.8.330

Common Name: Polymeric Surgical Mesh

Proprietary Name: T-Sling

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Device Description: The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).

Intended Use: T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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510(k) Number (if known) K050516

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(Per 21 CFR 801.109) (Optional Format 1-2-96)

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Coloplast

T-Sling

Fold

English

T-Sling

REF 519400

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Manufactured by:
Herniamesh S.r.l.
Via Fratelli Meliga 1/C
10034 Chivasso (To) - Italia

Distributor:
Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

Fold

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Sterilized Using Ethylene Oxide
Caution: Consult Accompanying Documents
Do Not Use If Package Is Damaged
Do Not Resterilize
Do Not Reuse

Caldera Medical, Inc. T-Sling
K050516 5

510(k) Summary

FEB 3 2006

Date of Summary:	January 19, 2006
Applicant:	Bryon L. Merade, CEO Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556
Contact:	Marla Kengen, Project Leader Caldera Medical, Inc. 28632 Roadside Drive, Suite 260 Agoura Hills, CA 91301 Tel: (866) 422-5337 Fax: (818) 879-6556 marla@calderamedical.com
Device Name:	Surgical Mesh (878.3300)
Trade Name:	T-Sling
Common Name:	Surgical Mesh
Classification:	Class II
Predicate Devices:	Herniamesh T-Sling – K020652 Tyco Healthcare IVS Tunneller – K010035 Ethicon TVT – K012628
Device Description:	The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).
Indications for Use:	The T-Sling is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K050516
Trade/Device Name: T-Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: November 28, 2005
Received: December 19, 2005

Dear Ms. Kengen:

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.

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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" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number: K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

Barbara Bradley

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

510(k) Number K050516

K050516/A2

(2nd copy - DXV)

January 19, 2005

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

Re: K050516/S001
T-Sling

Dear FDA Reviewer:

The attached document is in response to your request for additional information regarding the supplemental responses for two of the deficiencies noted in your letter of June 22, 2005 regarding Caldera Medical, Inc. T-Sling K050516.

The additional information attached is in regards to supplemental responses #10 b. & c.

After review of this additional information, if you have any questions please contact me at 818-879-6555.

Regards,

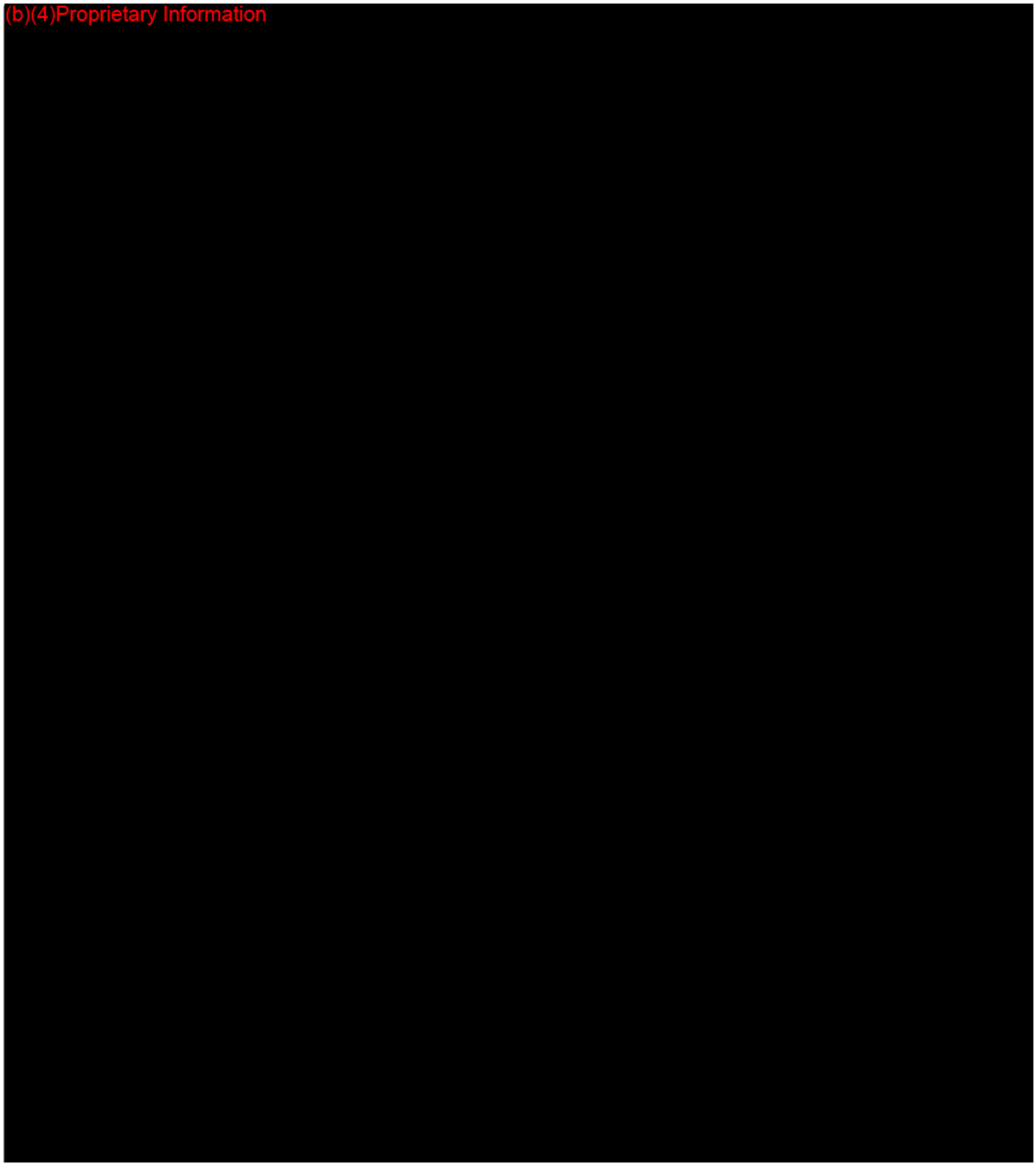
Marla Kengen

Marla Kengen
Project Leader

25 K23

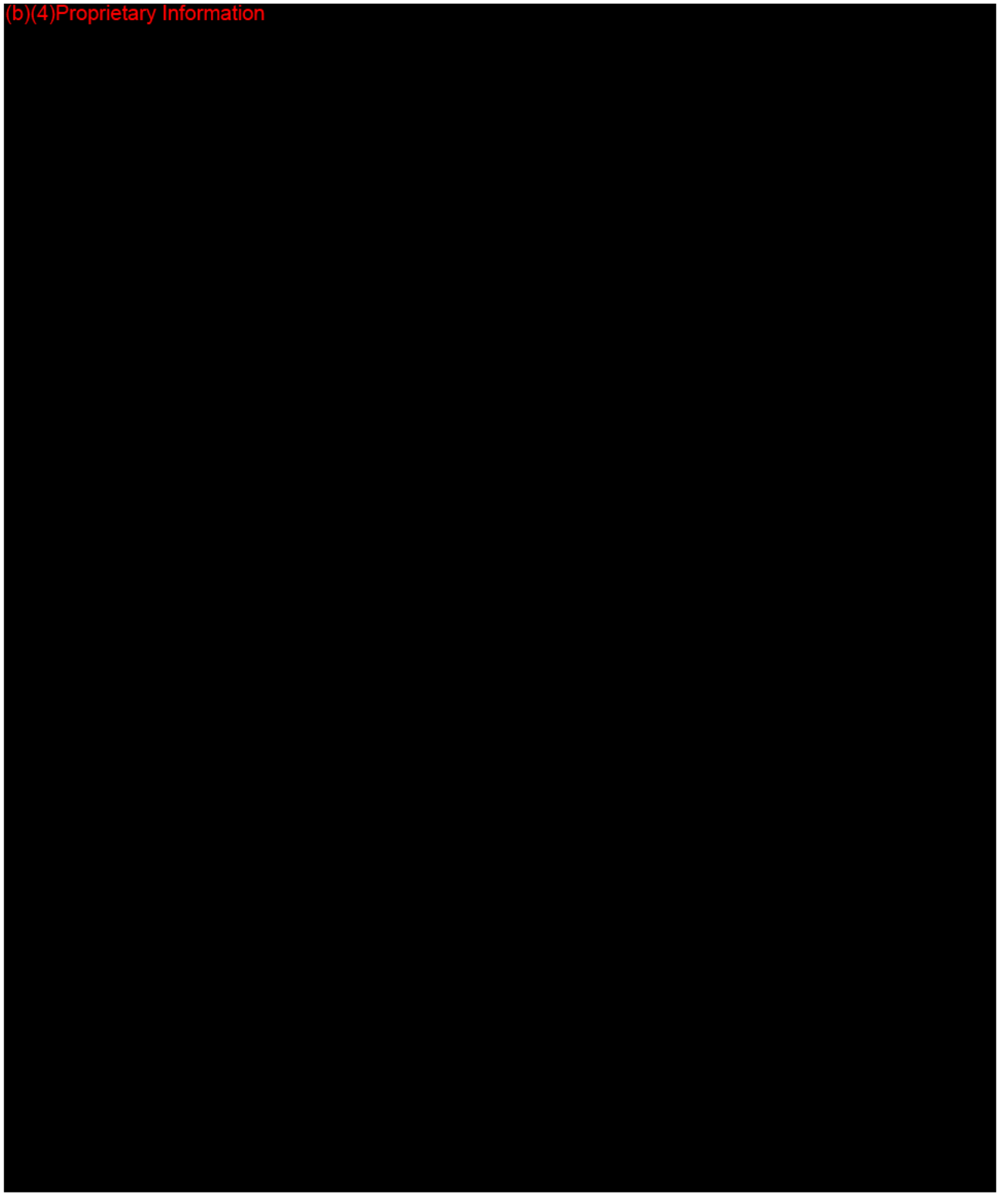
Re: K050516
Additional Information Requested
January 19, 2006

(b)(4)Proprietary Information



Re: K050516
Additional Information Requested
January 19, 2006

(b)(4)Proprietary Information



K050516/A3

Chivasso, February 26th, 2014

FDA
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: K050516/A003
T-Sling
510(k) number: K050516
Letter from CDRH received on: December 9, 2013

This add–to-file letter is in response to the letter we received from CDRH accepting our request of removing reference to vaginal prolapse repair from the Indication for Use statement of 510(k) K050516.

The add-to-file letter should be reviewed by the Office of Device Evaluation (ODE), Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Obstretics and Gynecology Devices Branch (OGDE).

Here attached:

- 510(k) Summary and Indication for Use Form
- IFU

The eCopy is an exact duplicate of the paper copy

Sincerely yours,

Eng. Roberta Lamberti
QARA and R&D Manager
Herniamesh S.r.l.

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 – C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

K050516 | A003

Chivasso, December 20th, 2013

FDA
k.a. Sharon M. Andrewws
Biomedical Engineer, DRUG/OGDB
10903 New Hampshire Avenue
WO66, Room G110
Silver Spring, MD 20993.

Re: PS130047
T-Sling
510(k) number: K050516
Letter from CDRH received on: December 9, 2013

This add–to-file letter is in response to the letter we received from CDRH accepting our request of removing reference to vaginal prolapse repair from the Indication for Use statement of 510(k) K050516.

The add-to-file letter should be reviewed by the Office of Device Evaluation (ODE), Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Obstretics and Gynecology Devices Branch (OGDE).

Here attached:

- Indication for Use Form
- 510(k) Summary
- Labelling

Sincerely yours,

Eng. Roberta Lamberti
QARA and R&D Manager
Herniamesh S.r.l.

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. - P.I. 02791540616 - C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

Submitter: Herniamesh SRL
Via Fratelli Meliga 1/C
Chivasso, Italy
Tel +39 011 9196236 Fax + 011 550 40 85

Contact: Lorena Trabucco
540 MUTTONTOWN EASTWOODS ROAD
Syosset, NY 11791
Tel 516 987-9364 – 516 584 6818
e-mail: lorenat63@aol.com

Date Prepared: December 20th, 2013

Classification: Polymeric Surgical Mesh (product code FTL) Class II device per 21 CFR 87.8.330

Common Name: Polymeric Surgical Mesh

Proprietary Name: T-Sling

Predicate Devices: **K020652** T-Sling (Herniamesh)
K010035 IVS Tunneller (Tyco Healthcare)
K012628 TVT (Ethiconl)

Device Description: The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).

Intended Use: T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Indications for Use Form

510(k) Number (if known) K050516

Device Name: T-Sling

Indications For Use:

T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use__x OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

HERNIAMESH SRL
Sede legale Via Fratelli Meliga 1/C – 10034 Chivasso (TO)
Cap. Soc. € 98.800 i.v. – P.I. 02791540616 – C. F. 02245180613 - N. Iscrizione Rea Torino TO-960622
Tel. +39-0119196236 – fax +39-0119196239
Mail: info@herniamesh.it - Mail certificata: amministrazione@pec.herniamesh.it - Sito internet www.herniamesh.com

English

T-Sling

REF 519400

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

Description
Non-absorbable knitted monofilament polypropylene mesh provided with protective sheaths and pre-assembled sutures.

Indications
T-Sling is a pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Sterilization
The **T-Sling** is sterilized with ethylene oxide.

Packaging
Each **T-Sling** sling is packed in a double blister, both shell are sealed by a Tyvek® film. Only the inner blister is sterile.

Storage
This product must be stored at room temperature, in a clean dry place. Do not expose the product to direct sunlight, humid environments or extreme temperatures.

Adverse Reactions
Potential adverse reactions are similar to those associated with other surgically implanted materials or devices. This may include infection, acute and chronic inflammation with possible functional alteration of the organs involved, adhesions, fistula formation, erosion and rejection. Perforations or laceration of blood vessels, nerves, bladder, bowel and uterus may occur during passage of needles and might require open surgical repair.

T-Sling

Manufactured by:
Hernia mesh S.r.l.
Via Fratelli Melga 1/C
10034 Chivasso (To) - Italia

Distributor:
Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark

Contraindications and Warnings ⚠

1.**T-Sling** will not stretch significantly and therefore this product should not be used in patients with potential growth and in women who are planning future pregnancies.

2.As with any suspension procedure, this product should not be used on patients who are taking anti-coagulants or anti-aggregating drugs, non-steroidal anti-inflammatory agents, or in patients that have any blood disease with hemorrhagic
tendencies.

3.The **T-Sling** must not be used in contaminated wounds; in presence of infections the removal of the sling may be required.

4.The **T-Sling** must not be placed in contact with the bowel or other viscera.

5.Excessive tension on the sling can cause obstruction of the urethra or of the lower urinary tract that, even if transitory, could result in postoperative urinary retention (anterior approach).

6.Surgeons who intend to use **T-Sling** must have experience of the different surgical techniques regarding the vaginal vault and bladder neck suspensions.

7.As in all suspension procedures, retropubic haemorrhaging may occur if the transvaginal approach is used. It is therefore necessary to monitor all the patient's symptoms relating to this phenomenon before her release from the hospital.

8.After positioning the sling with the anterior approach (transvaginal retro pubic), a cystoscopy must be performed in order to confirm the integrity of the bladder to locate a possible perforation. In the transobturator and posterior approach cystoscopy is at the discretion of the surgeon.

9.The vaginal vault suspension by posterior approach can be performed simultaneously with cystocele, rectocele and enterocele repair.

10.Do not implant using staples or clips this may cause mechanic
al damage to the sling.

11.Do not use in patients that have known allergies to polypropylene.

12.The **T-Sling** is a single-use product. Do not resterilize

13.Do not use the product if the Tyvek® pouch package has been opened or damaged, or after expiration date.

Product Traceability
Product traceability labels are included in every package and are used to identify type and lot number of the prosthesis. The label should be applied to the patient's medical records in order to clearly identify the product that was implanted.

Product Evaluation
Please contact Product Evaluations Department, Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free 800-338-7908.

Product Order Information or Returned Goods Authorization
Please call Customer Service Department, Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free (800) 258-3476.

References
Literature references are available upon request from:
Coloplast Customer Service
1601 West River Road North
Minneapolis, MN 55411 USA
Toll-free telephone (800) 258-3476

Sterilized Using Ethylene Oxide
Caution: Consult Accompanying Documents
Do Not Use If Package Is Damaged
Do Not Resterilize
Do Not Reuse

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Ms. Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, California 91301

Re: K050516
Trade/Device Name: T-Sling
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM
Dated: November 28, 2005
Received: December 19, 2005

Dear Ms. Kengen:

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" (21 CFR 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Form

510(k) Number: K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

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

510(k) Number K050516

3

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 19, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

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 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

24

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

September 02, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

Extended Until: 22-DEC-2005

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

120

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 22, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

Extended Until: 22-SEP-2005

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

121

August 16, 2005

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

Re: K050516/S001
T-Sling
Request "Extended Until" Date

Dear FDA Reviewer:

(b)(4)Proprietary Information

[redacted]

Sincerely,

Marla Kengen

Marla Kengen
Project Leader

K27

122

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

July 18, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

Extended Until: 22-AUG-2005

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information is not received by the "Extended Until" date shown above your premarket notification will be considered withdrawn.

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

123

July 12, 2005

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

Re: K050516/S001
T-Sling
Request for 30 Day Extension

Dear FDA Reviewer:

(b)(4)Proprietary Information

[redacted]

Sincerely,

Marla Kengen

Marla Kengen
Project Leader

SK 43

124

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2005

Ms. Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hill, California 91301

Re: K050516/S001
Trade Name: T-Sling
Dated: April 7, 2005
Received: April 12, 2005

Dear Mrs. Kengen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require you provide additional information to the following listing of deficiencies to determine the degree of equivalency of your device with the predicates.

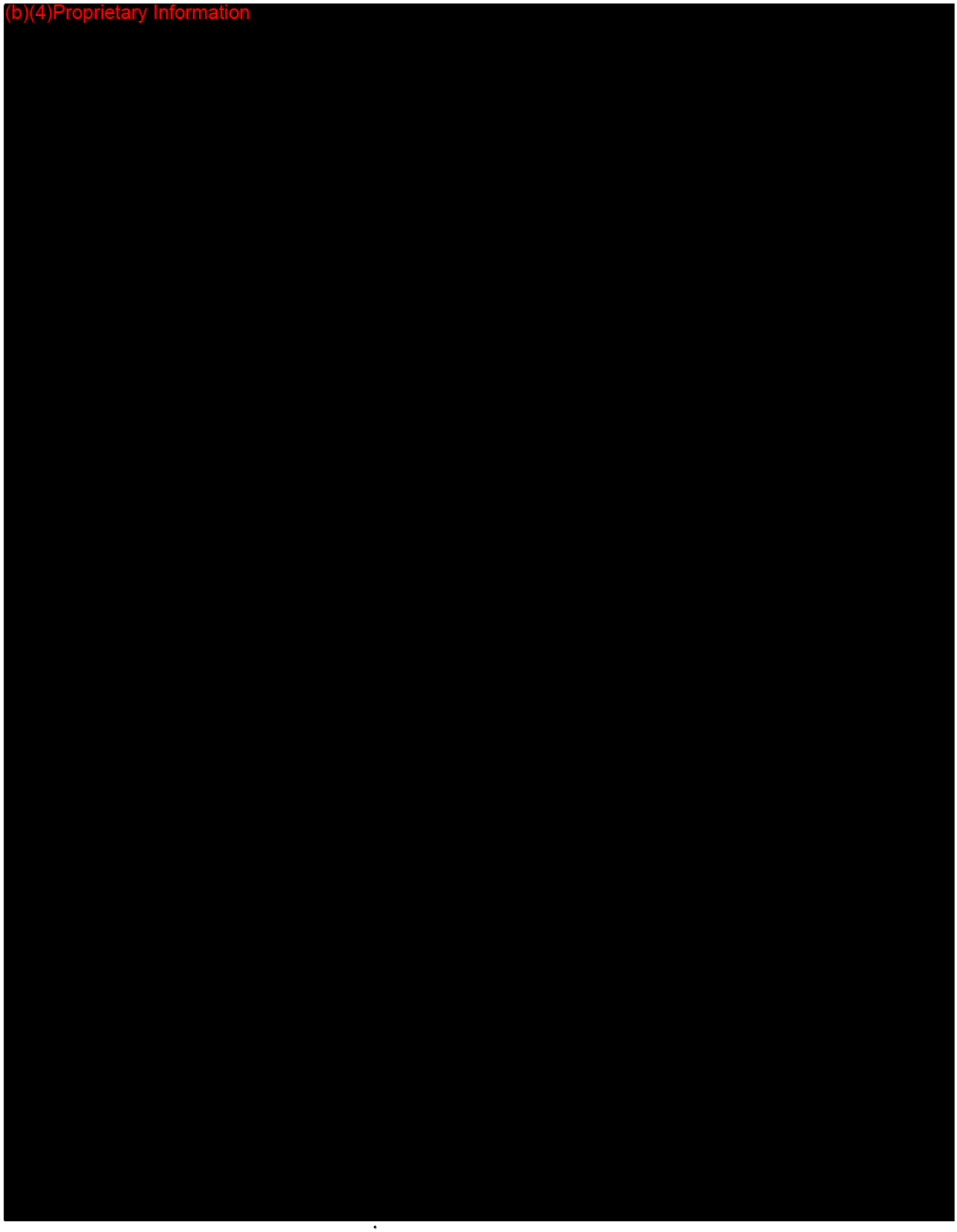
Deficiencies

(b)(4)Proprietary Information

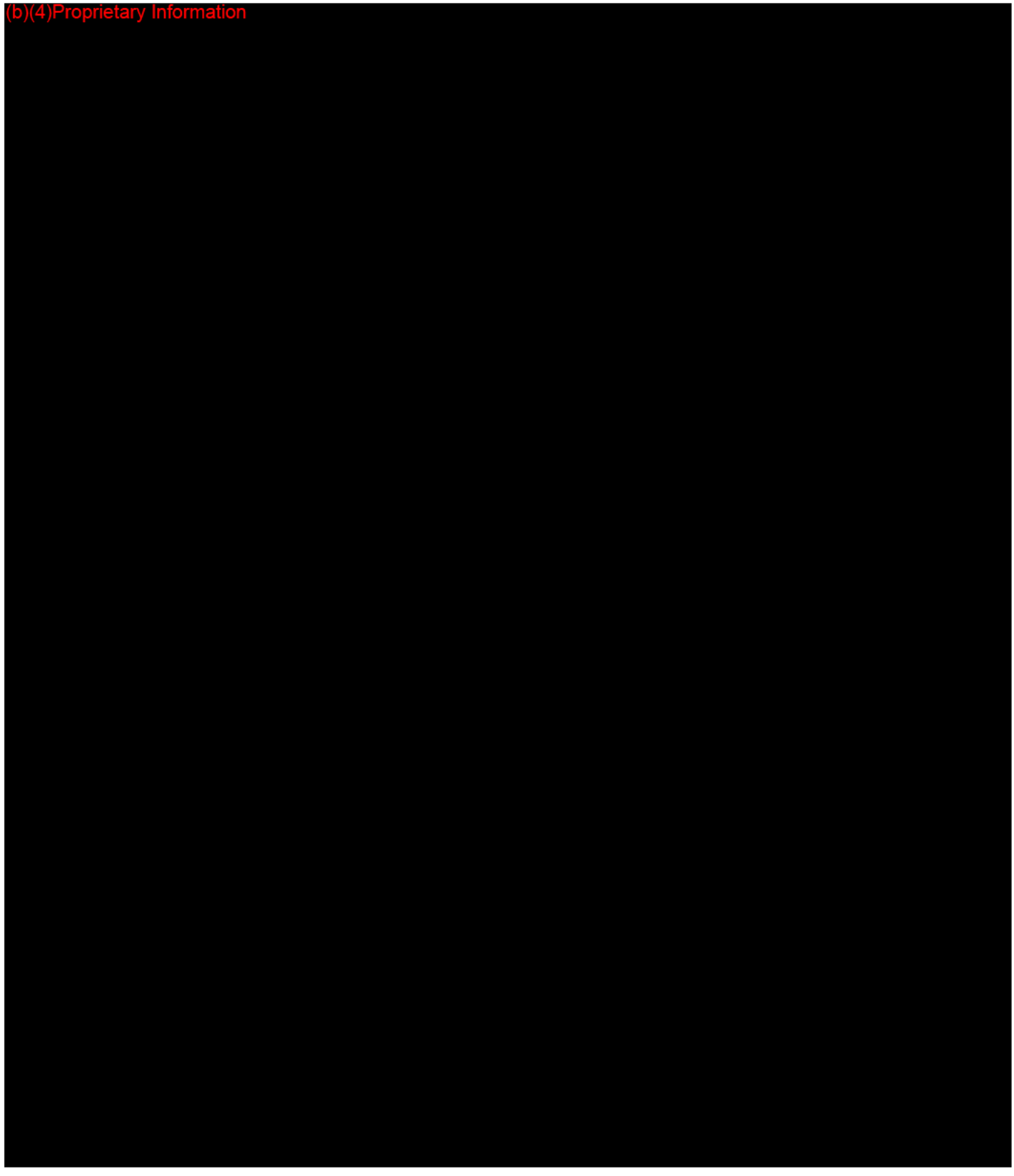
[redacted]

125

(b)(4)Proprietary Information



(b)(4)Proprietary Information



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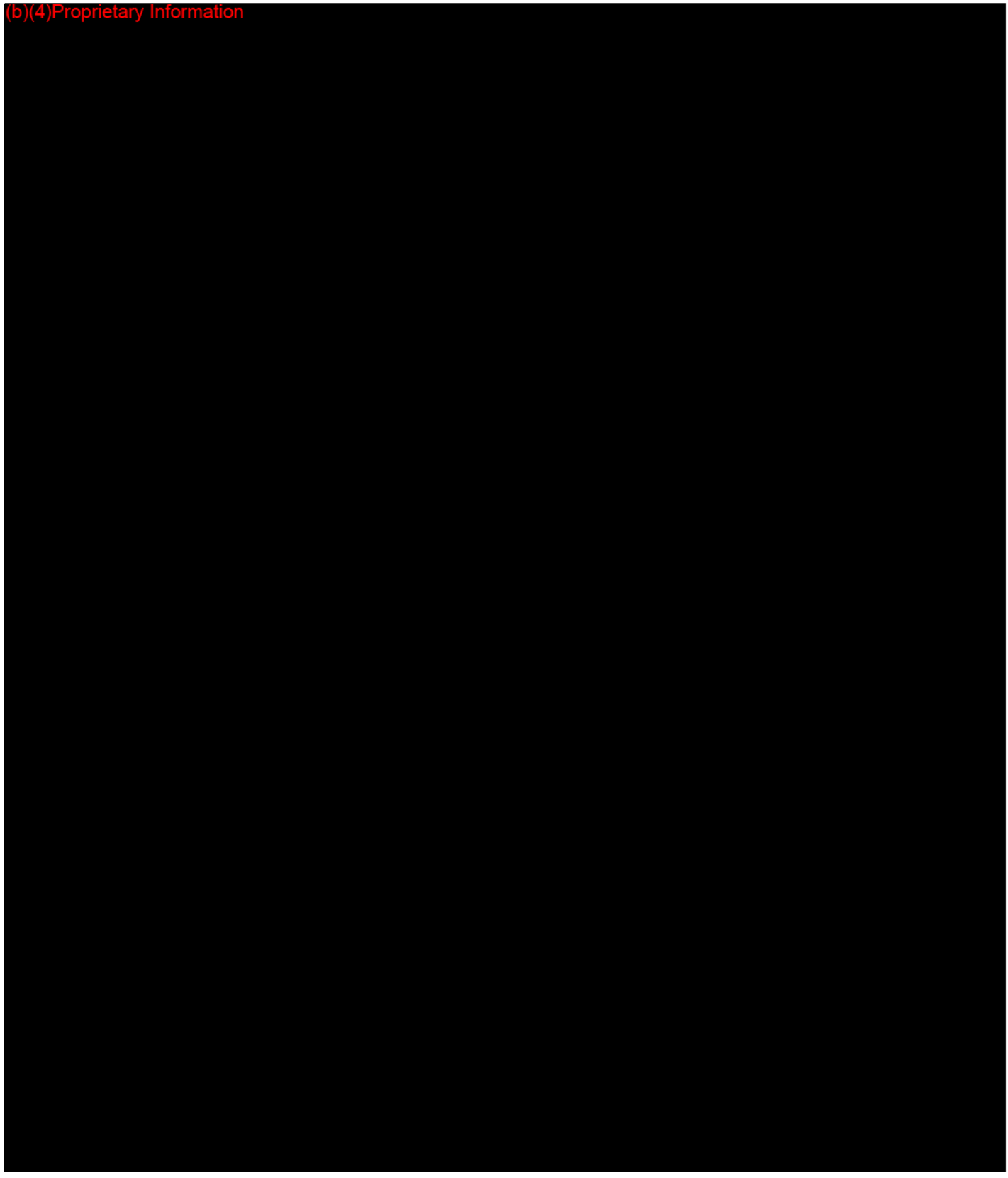


The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Dora Vega, M.D., PhD. at (301) 594-3090 – ext 142. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

JUN 2 2 2005

Ms. Marla Kengen
Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hill, California 91301

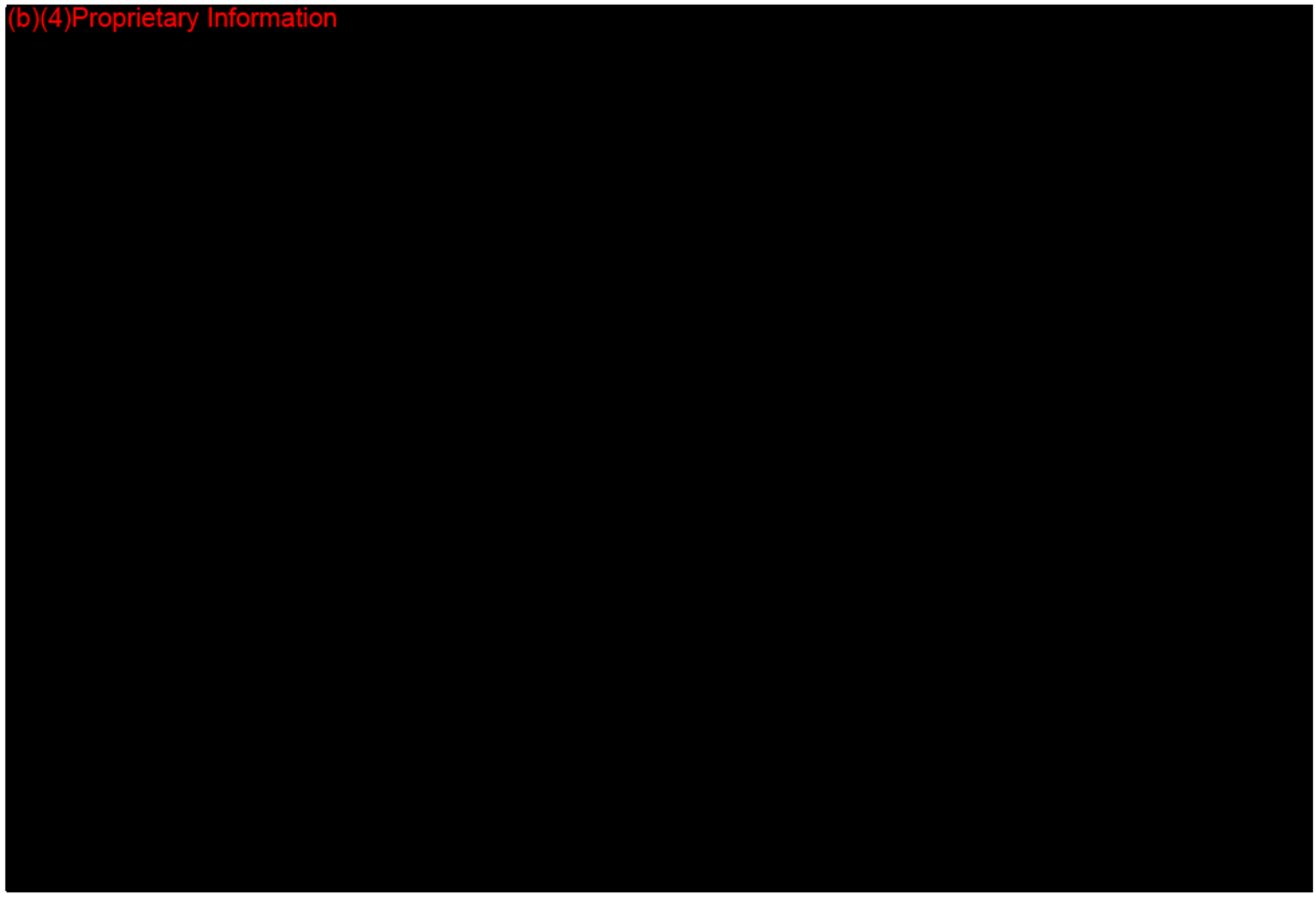
Re: K050516/S001
Trade Name: T-Sling
Dated: April 7, 2005
Received: April 12, 2005

Dear Mrs. Kengen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require you provide additional information to the following listing of deficiencies to determine the degree of equivalency of your device with the predicates.

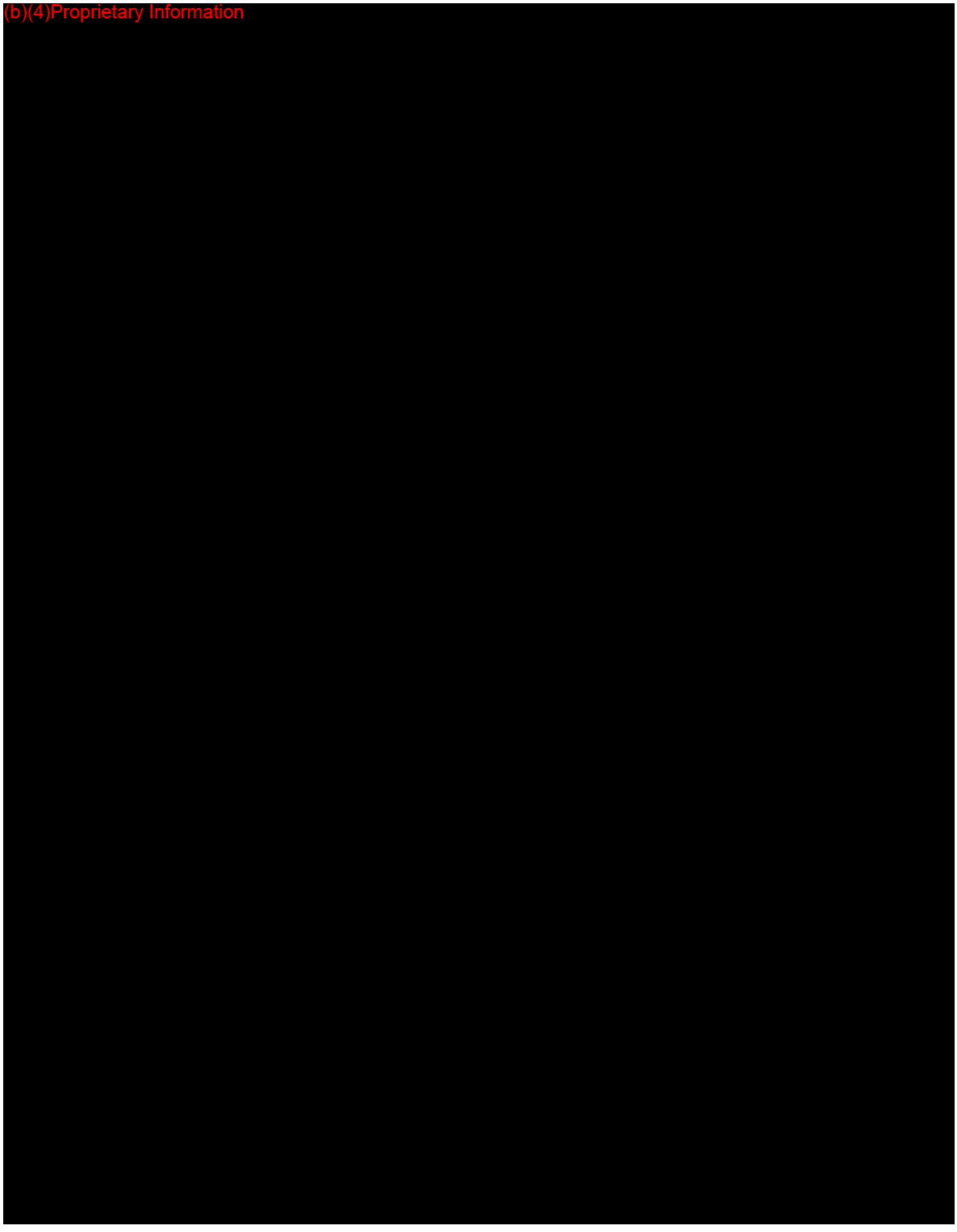
Deficiencies

(b)(4)Proprietary Information



130

(b)(4)Proprietary Information



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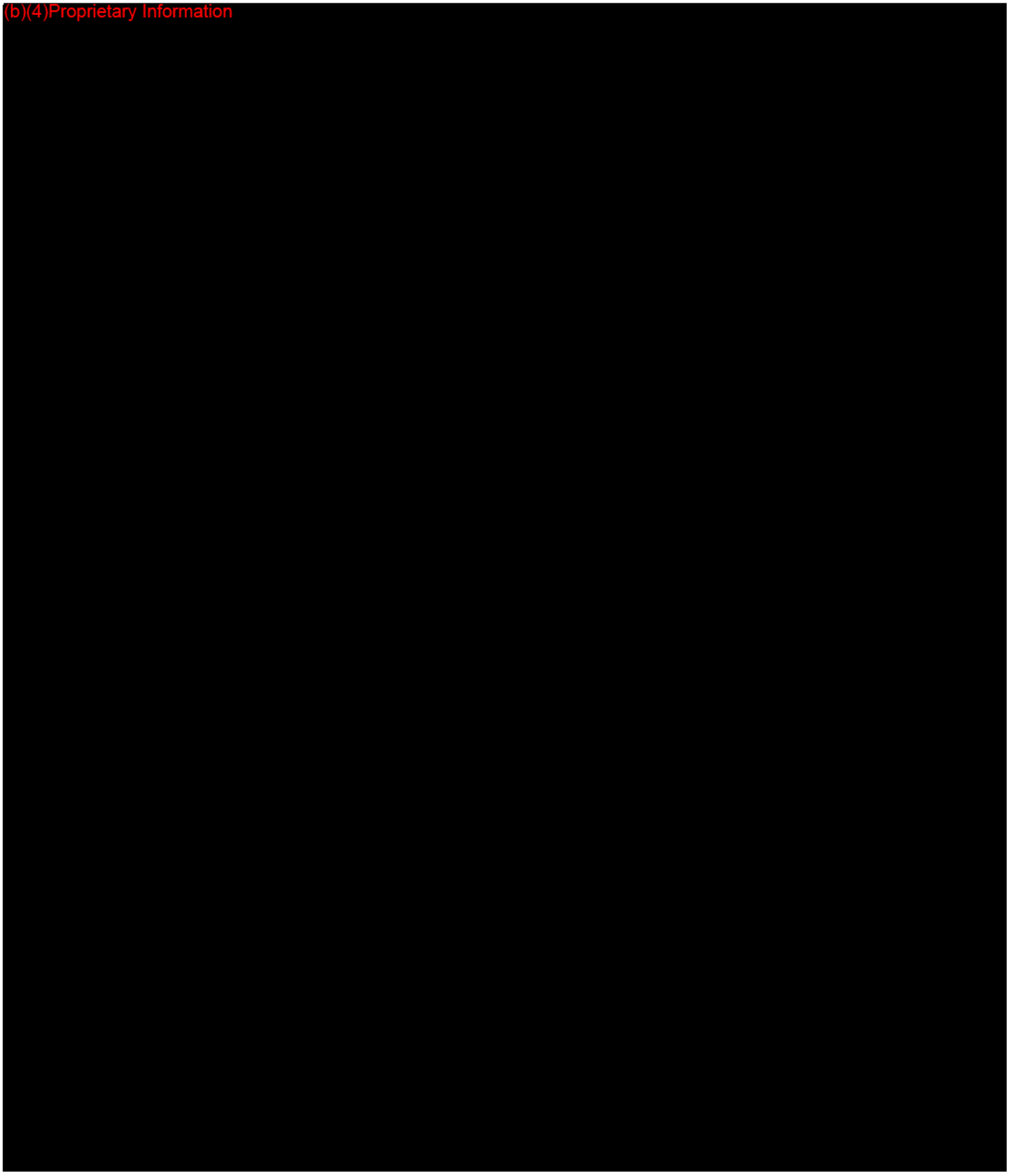

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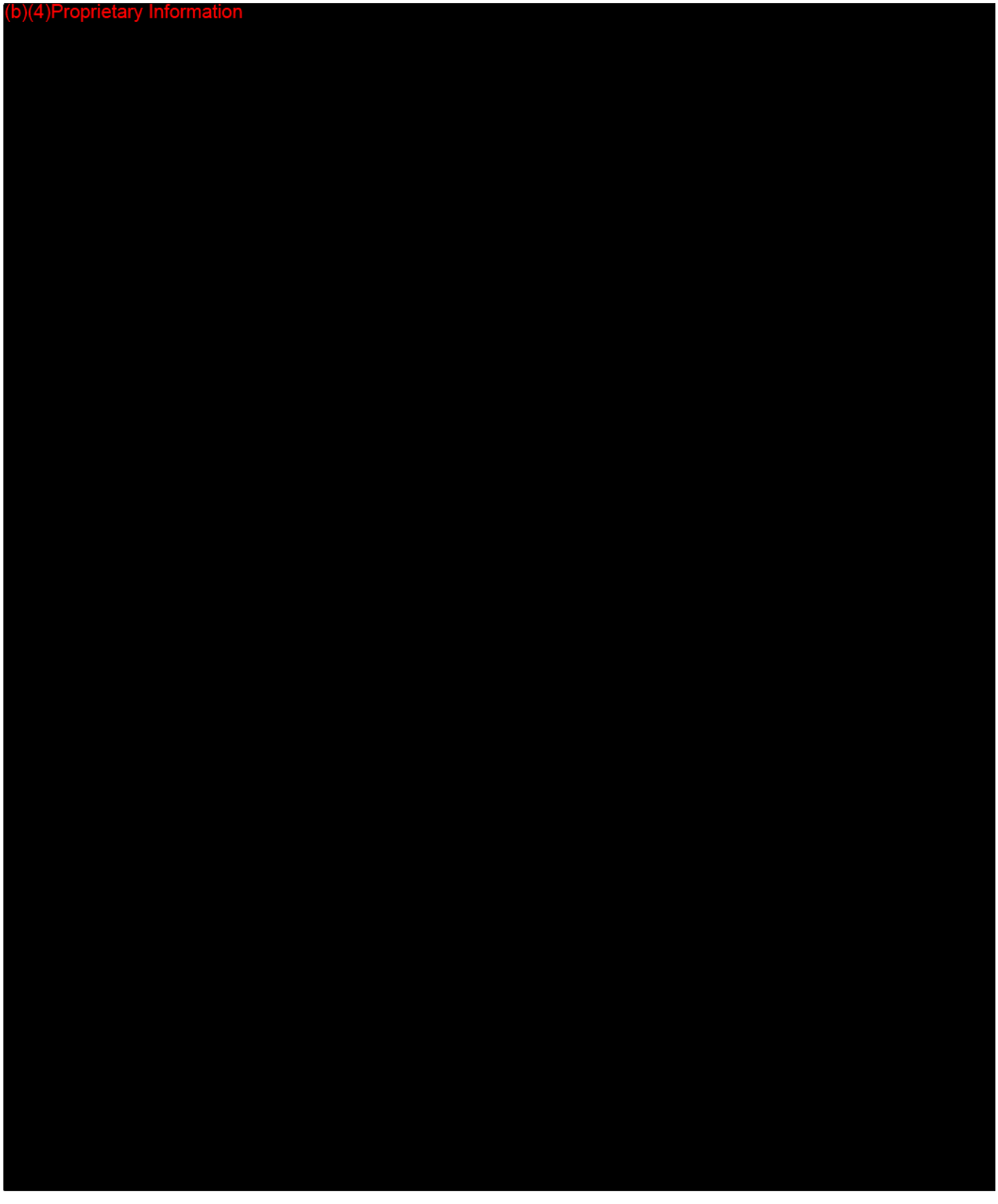


The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

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

If you have any questions concerning the contents of the letter, please contact Dora Vega, M.D., PhD. at (301) 594-3090 – ext 142. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

134

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND
D.O.

f/t:DVega:tmj:6-22-05

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

March 21, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

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. Please note our guidance document entitled, "Guidance for Industry and FDA Staff 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. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. 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.

156

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

March 04, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Received: 03-MAR-2005
Product: T-SLING

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. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a 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. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

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 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 regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

166

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

March 01, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Received: 01-MAR-2005
Product: T-SLING
User Fee ID Number: 17379

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

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier (e.g., Fed Ex, UPS, etc.)

U.S. Bank
956733
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.

167

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

K000516

New Premarket Notification for T-Sling

Table of Contents

Topic	Page
Truthful and Accurate Statement	1
Applicant	2
Contact	2
Device Name	2
Trade Name	2
Common Name	2
Classification	2
Registration Number	2
Manufacturing Site	2
Sterilization Site	2
Device Description	2
Comparison to Predicate Devices	2
Statement of Indication for Use	3
Technological Characteristics	3
Scanning electron Microscopy Pictures of T-Sling	3
Dimensions of T-Sling	3
Attachment # 1: Indications for Use Form	4
Summary of Safety and Effectiveness	5-6
Exhibit 1: 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)	7
Table of Similarities and Differences / Substantial Equivalence to Predicate Devices	8-9
Safety, Efficacy and Performance Results	10
Ethylene Oxide Residual	10
Sterility Assurance level	10
Ethylene Chlorohydrin Level	10
Sterilization Validation Protocol	10
Copy of CE Certification for T-Sling	11
Performance Tests	12-68
T-Sling Packaging And Labeling ([redacted])	69
T-Sling Packaging And Labeling [redacted]	69
T-Sling Packaging And Labeling [redacted]	70-71
Brochure / Technical Information for T-Sling	72-75
T-Sling Instructions for Use	76
Labeling of Predicate Device: [redacted]	77
Labeling of Predicate Device: [redacted]	78
Brochure / Technical Information of Predicate Device: [redacted]	79-84
Instructions for Use of Predicate Device: [redacted]	85-89
Instructions for Use of Predicate Device: [redacted]	90
Articles on [redacted]	[redacted]

Sh 33

169

Premarket Notification
Truthful and Accurate Statement
[As required by 21 CFR 807.87 (i) I]

I certify that, in my capacity as Chief Executive Officer of Caldera Medical, 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.

Bryon L. Merade, CEO

Date: 2/24/05

510 (k) #: ______________

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)Proprietary Information
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

CALDERA MEDICAL, INC.
28632 ROADSIDE DRIVE
SUITE 260
AGOURA HILLS, CA 91301

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)

2. CONTACT NAME
MARLA KENGEN

2.1 E-MAIL ADDRESS
marla@calderamedical.com

2.2 TELEPHONE NUMBER (Include Area Code)
818-879-6555

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
818-879-6556

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4)Proprietar

Form FDA 3601 (08/2003)

171

New 510 (k) Notification for T-Sling

Date of Application: February 22, 2005

Applicant:
Bryon L. Merade, CEO
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556

Contact:
Marla Kengen
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556
marla@calderamedical.com

Device Name: Surgical Mesh (878.3300)

Trade Name: T-Sling

Common Name: Surgical Mesh

Classification: Class II

Registration Number: 9054589

Manufacturing Site: (b)(4)Proprietary Information

Sterilization Site: (b)(4)Proprietary Information

Device Description
The T-sling dual component prosthesis (absorbable & non-absorbable) is made of monofilament polypropylene and polydioxanone warp knitted into a composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency, and vaginal vault prolapse.

Comparison to Predicate Devices
The T-sling mesh is substantially equivalent in design and function to the I.V.S. Tunneller (K010035) and GYNECARE Tension Free Vaginal Tape (TVT) (K012628).

Name of Predicate Device	Manufacturer / Town & State	510 (k) Number
I.V.S. Tunneller	Tyco Healthcare Group L.P. Norwalk, CT	K010035
GYNECARE Tension Free Vaginal Tape (TVT)	Ethicon Inc. Somerville, NJ	K012628

Premarket Notification for T-Sling

Statement of Indication for Use

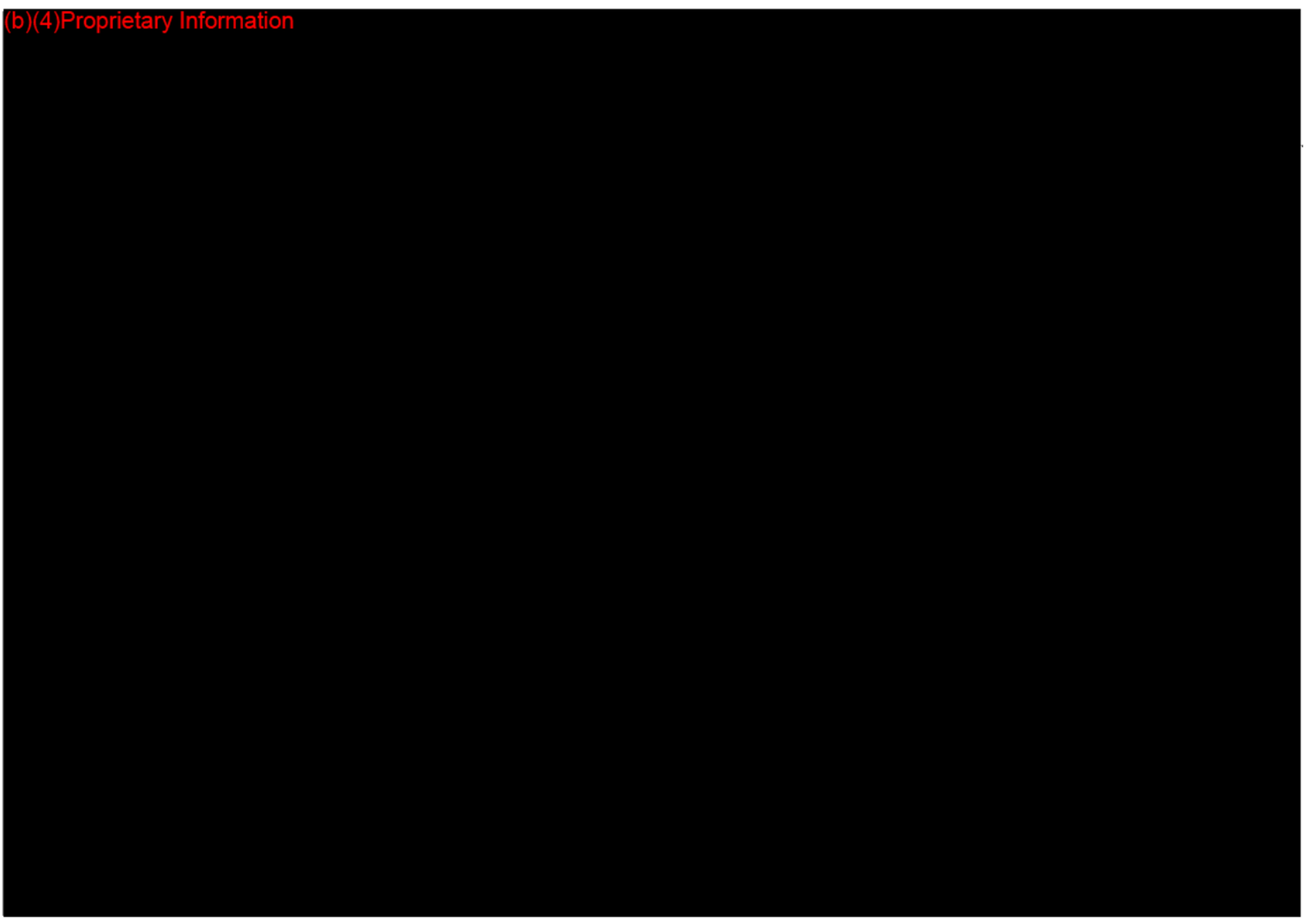
The T-sling is a dual-component pubourethral sling for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Technological Characteristics

Technologically the T-Sling and predicate devices are the same (i.e. all are meshes that provide pubourethral support). The bioabsorbable portion of the T-Sling is biocompatible and is made from the same materials widely used as absorbable sutures and clips. Any differences between the T-Sling and predicate devices do not raise new questions of safety and effectiveness.

Scanning electron Microscopy Pictures of T-Sling

(b)(4)Proprietary Information



Attachment # 1

Indications for Use Form

510(k) Number: K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a polypropylene mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

Caldera Medical, Inc. T-Sling
K050516 5
510(k) Summary

Date of Summary: January 19, 2006

Applicant:
Bryon L. Merade, CEO
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556

Contact:
Marla Kengen, Project Leader
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Tel: (866) 422-5337 Fax: (818) 879-6556
marla@calderamedical.com

Device Name: Surgical Mesh (878.3300)

Trade Name: T-Sling

Common Name: Surgical Mesh

Classification: Class II

Predicate Devices:
Herniamesh T-Sling – K020652
Tyco Healthcare IVS Tunneller – K010035
Ethicon TVT – K012628

Device Description: The T-Sling is made of monofilament polypropylene warp knitted into composite mesh construction. The T-Sling is a sterile, single-use pubourethral sling for the treatment of stress urinary incontinence (SUI).

Indications for Use: The T-Sling is intended to be used in females to position a mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

Summary of Safety and Effectiveness

The T-Sling is substantially equivalent to the I.V.S. Tunneller (K010035) currently marketed by Tyco Healthcare Group L.P and GYNECARE Tension Free Vaginal Tape (TVT) (K012628) currently marketed by Ethicon Inc. The 510 (k) "Substantial Equivalence" Decision-Making Process (detailed)" was utilized to make a determination of substantial equivalence (see Exhibit 1). Answers to the following questions have lead to a determination of substantial equivalence.

1. Does the new device have the same indication statement?

T-Sling has the same intended use as the I.V.S. Tunneller, which is for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency, and vaginal vault prolapse. Therefore, the T-Sling has the same intended use as the I.V.S. Tunneller and is considered to be "substantially equivalent."

2. Does the new device have same technological characteristics, e.g. design, materials, indication etc?

No, T-Sling has different technological characteristics. However, the technological differences meet or exceed the functional requirements of surgical meshes compared to the predicate devices. Please refer to Table of Similarities and Differences / Substantial Equivalence to Predicate Devices.

3. Could the new technological characteristics affect safety and effectiveness?

Yes, the new technological characteristics could affect safety and effectiveness. The differences in safety and effectiveness meet or exceed the requirements of surgical meshes compared to predicate devices.

4. Do the new characteristics raise new types of safety or effectiveness questions?

No, the safety and effectiveness questions are not new and include issues such as materials, pore size, tensile strength, suture retention, and biocompatibility. Sufficient data has been provided in this premarket notification to address any new safety and efficacy questions. Additionally, there are a variety of other meshes currently on the market with different characteristics compared to the T-Sling or the predicate devices.

Summary of Safety and Effectiveness (continued)

5. Do accepted scientific methods exist for assessing the effects of the new characteristics?

Yes. The effects of the new characteristics of the T-Sling can be assessed by common methods utilized for surgical meshes. These include mechanical testing, scanning electron microscopy, biocompatibility and in vivo safety and effectiveness testing.

6. Are performance data available to assess the effects of the new characteristics?

Yes. These tests include mechanical testing, scanning electron microscopy, biocompatibility testing and in vivo testing.

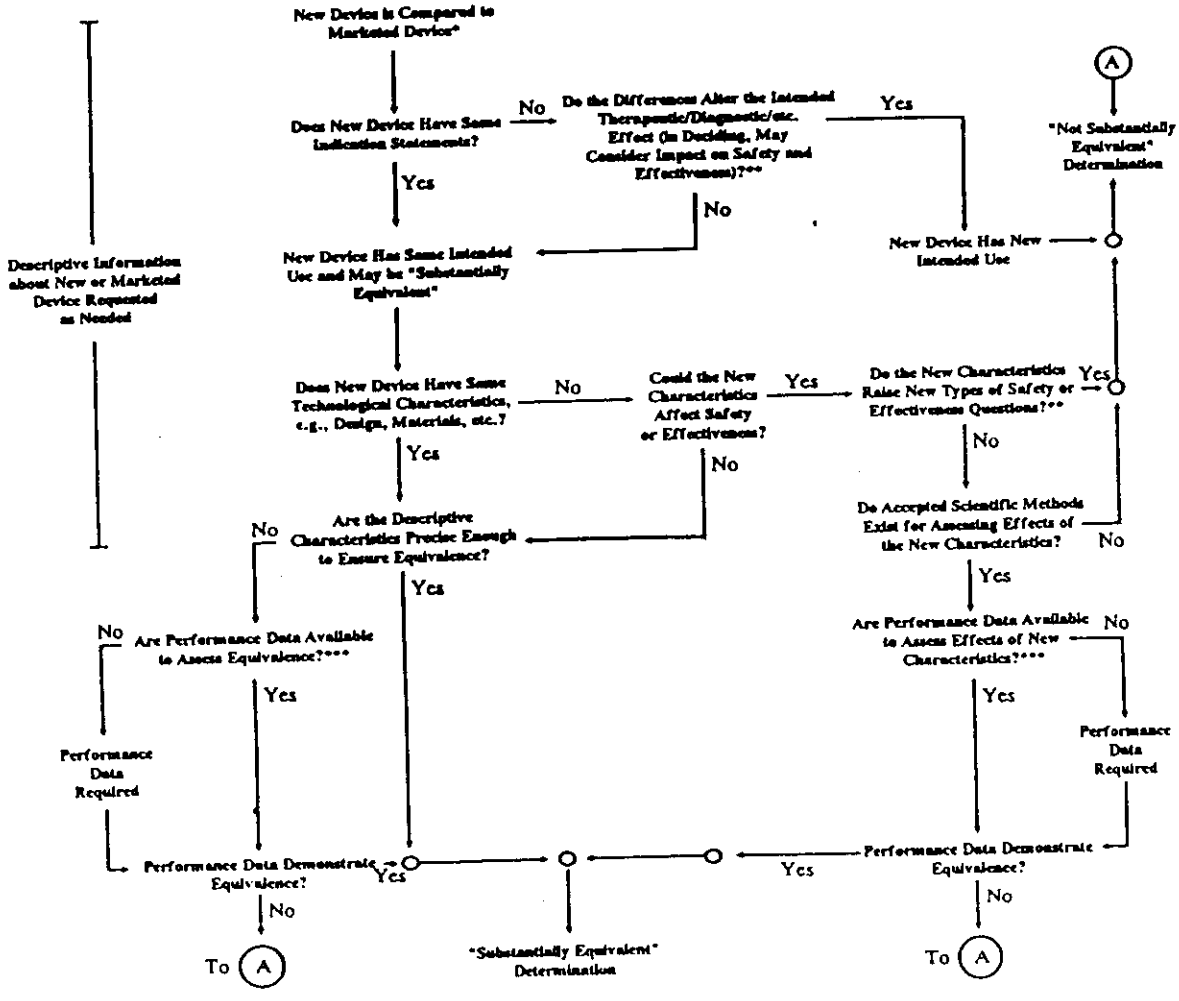
7. Do performance data demonstrate equivalence?

Yes. The physical and mechanical characteristics of the T-Sling meet or exceed those of the predicate devices. Please refer to Table of Similarities and Differences / Substantial Equivalence to Predicate Devices.

Based on this information the T-Sling is determined to be substantially equivalent to the predicate devices.

Exhibit 1

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



- 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

Feature	T-Sling	Ethicon TVT	Tyco Healthcare IVS Tunneller
510(k) No.	To be determined	K012628	K010035
Classification	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh
Indication	Intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse	Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency	Intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse
Product Desig	(b)(4)Proprietary Information	Pre-shaped Polypropylene mesh	Pre-shaped Polypropylene mesh
Materials	Polypropylene & (b)(4)Proprietary Information	Polypropylene	Polypropylene
Sterilization	EtO	EtO	EtO
Packaging	(b)(4)Proprietary Information	PVC tray with Tyvek back	Substantially Equivalent
Size	(b)(4)Proprietary Information	1.1cm x 45cm	Substantially Equivalent

Table of Similarities and Differences / Substantial Equivalence to Predicate Devices (Continued)

Feature	T-Sling	Ethicon TVT	Tyco Healthcare IVS Tunneller
Burst Strength	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Suture Retention	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Pore Size	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent
Tensile Strength	Substantially Equivalent	Substantially Equivalent	Substantially Equivalent

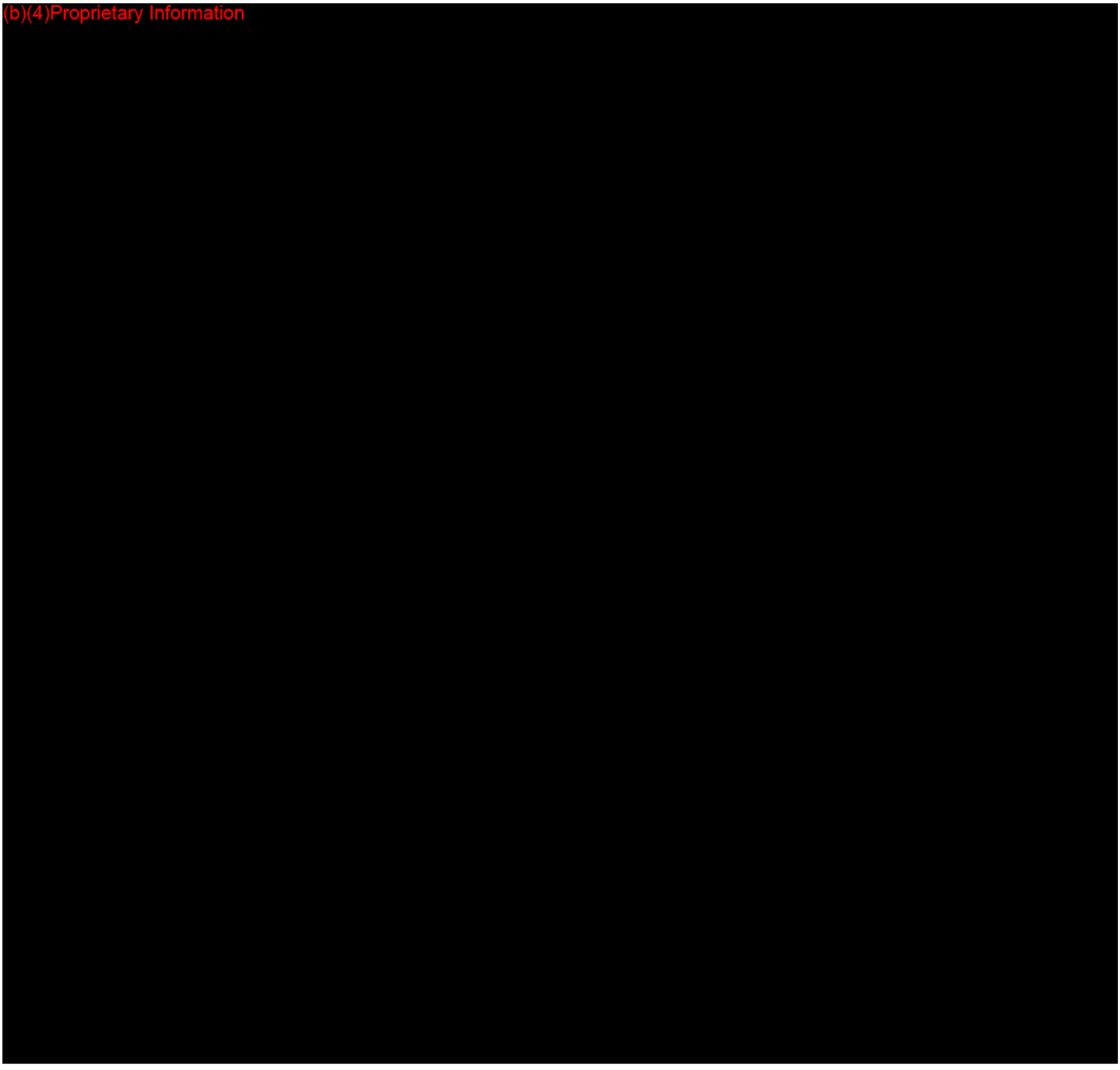
Safety, Efficacy and Performance Results

The following tests were performed to show the safety, efficacy and performance of T-Sling.

(b)(4)Proprietary Information

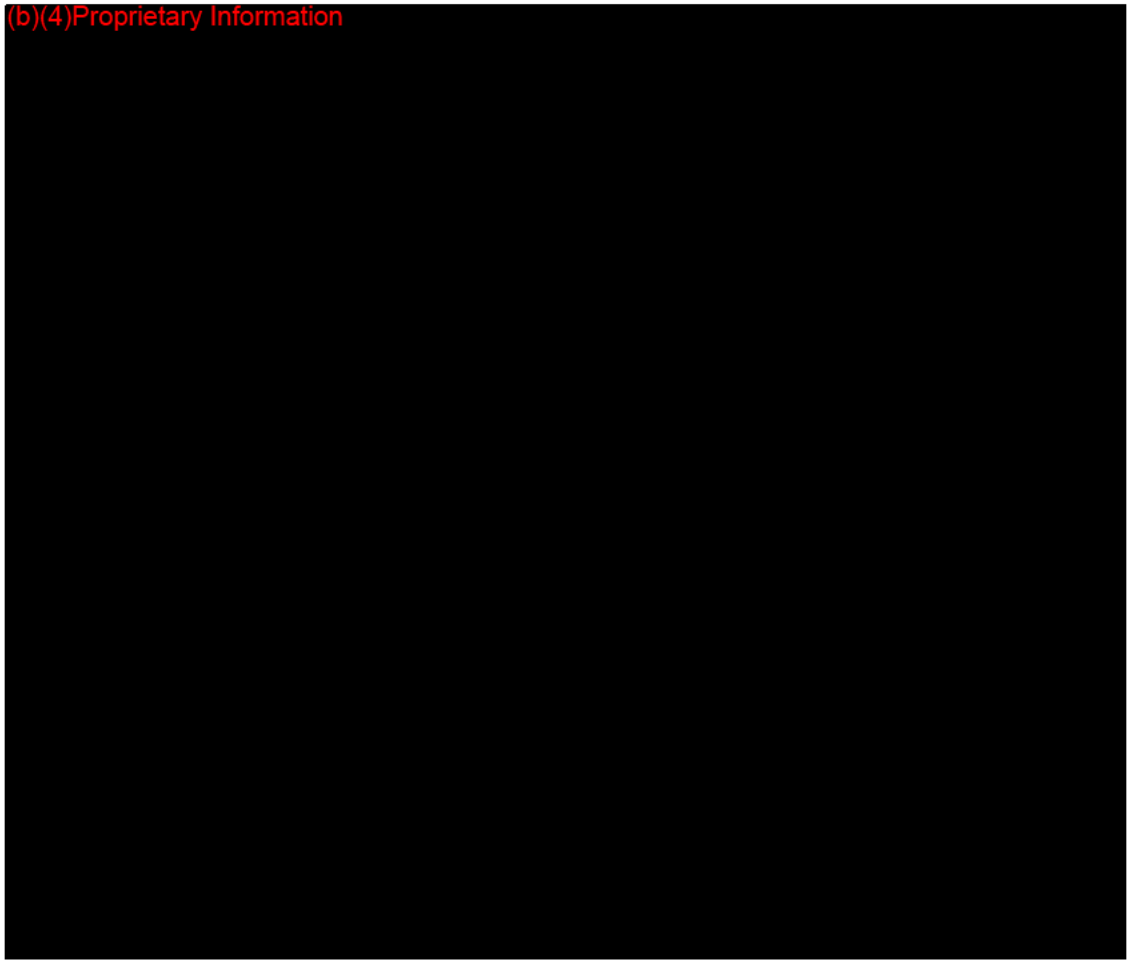
Copy of CE Certification for T-Sling

(b)(4)Proprietary Information



Performance Tests

(b)(4)Proprietary Information



(b)(4)Proprietary Information-Testing

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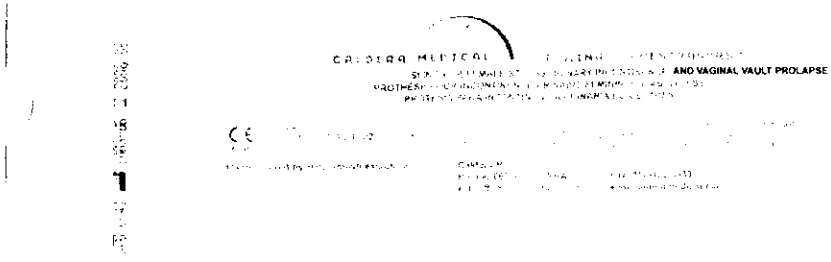
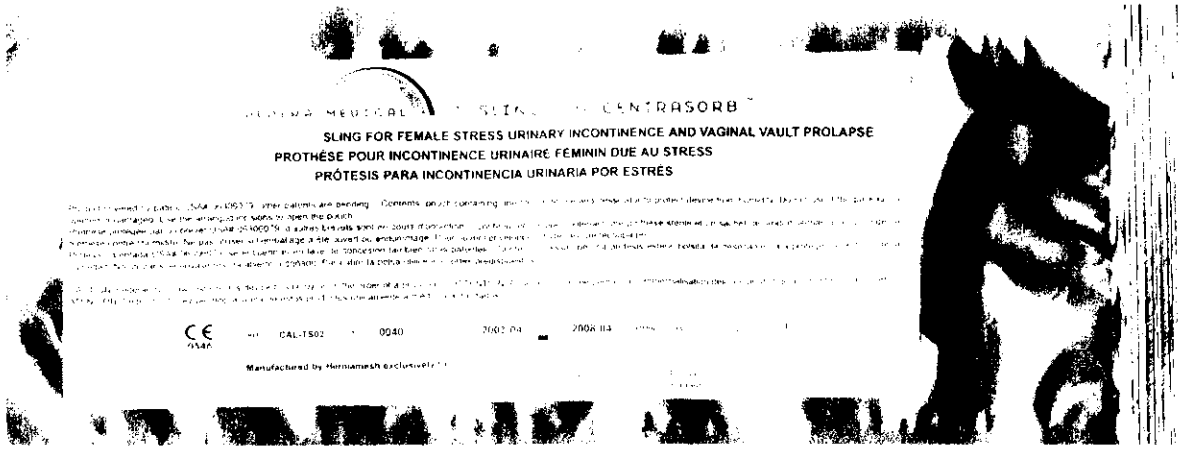
Premarket Notification for T-Sling

T-Sling Packaging And Labeling (Inner Tyvek Pouch)



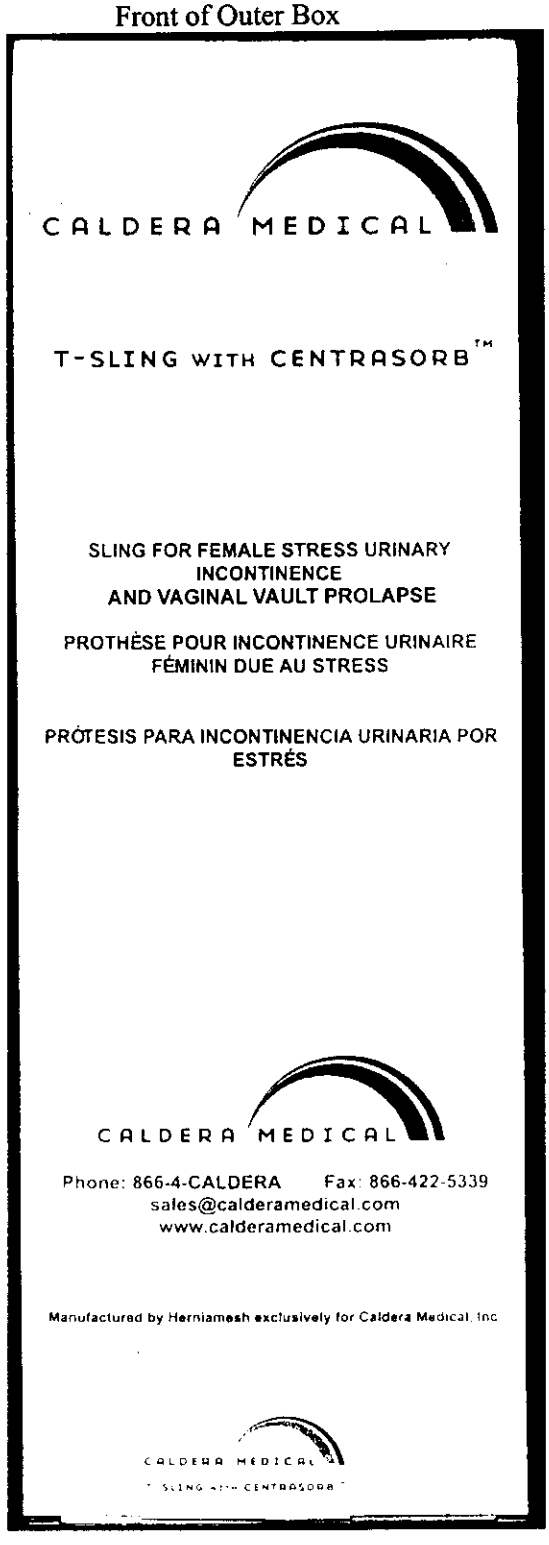
T-Sling Packaging And Labeling (Outer Foil Pouch)



Premarket Notification for T-Sling

T-Sling Outer Box Labeling (packaged 5 / box)

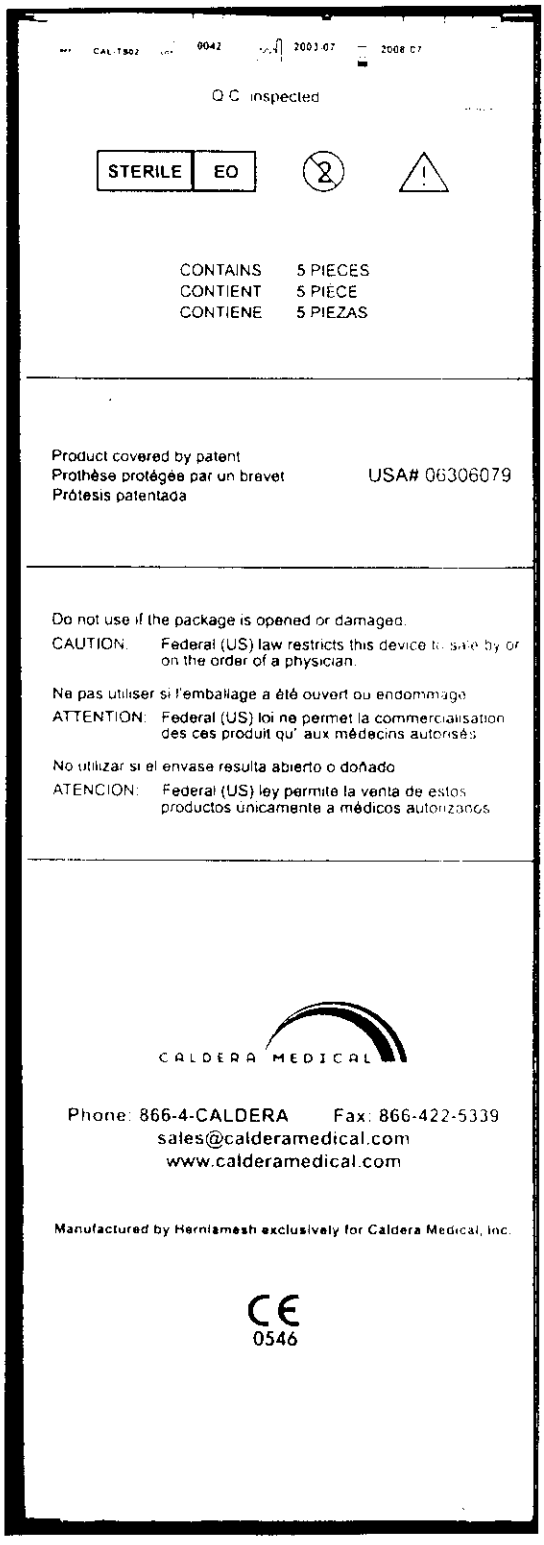
Front of Outer Box



Premarket Notification for T-Sling

T-Sling Outer Box Labeling (packaged 5 / box)

Back of Outer Box



(b)(4)Proprietary Information-Technical specs

(b)(4)Proprietary Information-Technical specs

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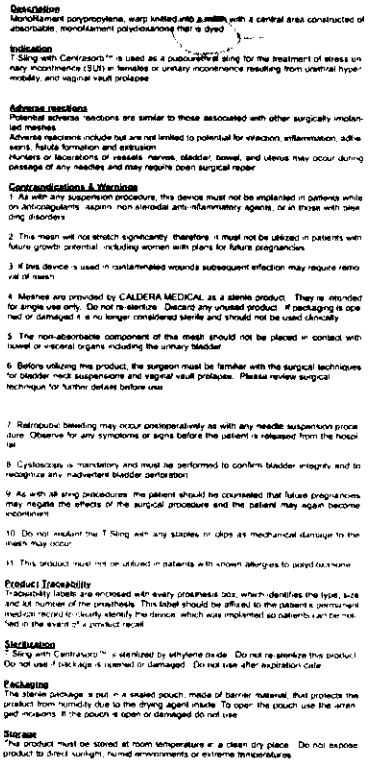
Premarket Notification for T-Sling

T-Sling Instructions for Use



Description
Monofilament polypropylene, warp knitted into a matrix with a central area constructed of absorbable, monofilament polydioxanone that is dyed

Indication
T-Sling with Centrasorb™ is used as a suburethral sling for the treatment of stress urinary incontinence (SUI) in females or urinary incontinence resulting from urethral hypermobility, and vaginal vault prolapse

Adverse reactions
Potential adverse reactions are similar to those associated with other surgically implanted meshes
Adverse reactions include but are not limited to potential for infection, inflammation, adhesions, fistula formation and extrusion
Hurters or lacerations of vessels, nerves, bladder, bowel, and uterus may occur during passage of any needles and may require open surgical repair

Contraindications & Warnings
1. As with any suspension procedure, this device must not be implanted in patients while on anti-coagulants, aspirin, non-steroidal anti-inflammatory agents, or in those with bleeding disorders

2. This mesh will not stretch significantly, therefore it must not be utilized in patients with future growth potential, including women with plans for future pregnancies

3. If this device is used in contaminated wounds subsequent infection may require removal of mesh

4. Meshes are provided by CALDERA MEDICAL as a sterile product. They are intended for single use only. Do not re-sterilize. Discard any unused product. If packaging is opened or damaged it is no longer considered sterile and should not be used clinically

5. The non-absorbable component of the mesh should not be placed in contact with bowel or visceral organs including the urinary bladder

6. Before utilizing this product, the surgeon must be familiar with the surgical techniques for bladder neck suspensions and vaginal vault prolapse. Please review surgical technique for further details before use

7. Retropubic bleeding may occur postoperatively as with any needle suspension procedure. Observe for any symptoms or signs before the patient is released from the hospital

8. Cystoscopy is mandatory and must be performed to confirm bladder integrity and to recognize any inadvertent bladder perforation

9. As with all sling procedures, the patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent

10. Do not implant the T-Sling with any staples or clips as mechanical damage to the mesh may occur

11. This product must not be utilized in patients with known allergies to polydioxanone

Product Traceability
Traceability labels are enclosed with every prosthesis pack, which identifies the type, size and lot number of the prosthesis. This label should be affixed to the patient's permanent medical record to clearly identify the device which was implanted so patients can be notified in the event of a product recall

Sterilization
T-Sling with Centrasorb™ is sterilized by ethylene oxide. Do not re-sterilize this product. Do not use if package is opened or damaged. Do not use after expiration date

Packaging
The sterile package is put in a sealed pouch, made of barrier material, that protects the product from humidity due to the drying agent inside. To open the pouch use the arrowed indicators. If the pouch is open or damaged do not use

Storage
The product must be stored at room temperature in a clean dry place. Do not expose product to direct sunlight, humid environments or extreme temperatures

ET061 Rev. A

CALDERA MEDICAL

T-SLING WITH CENTRASORB

SLING FOR FEMALE STRESS URINARY INCONTINENCE AND VAGINAL VAULT PROLAPSE

PROTHÈSE POUR INCONTINENCE URINAIRE FÉMININ DUE AU STRESS

PRÓTESIS PARA INCONTINENCIA URINARIA POR ESTRÉS

CALDERA MEDICAL
Phone [illegible]-CALDERA Fax 866-422-5333
sales@calderamedical.com
www.calderamedical.com

Manufactured by Herniamesh exclusively for Caldera Medical, Inc.

CE 0546

Premarket Notification for T-Sling

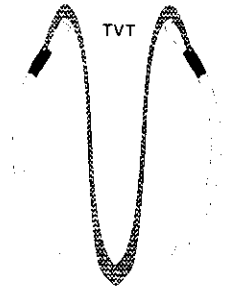
Labeling of Predicate Device: TVT by Ethicon Inc. (PVC tray with Tyvek back)

Premarket Notification for T-Sling

Labeling of Predicate Device: TVT (outer box)

810041
1.1cm x 45cm (0.5in. x 18in.)
1 Packet / 1 Sachet
1 Stück / 1 Confezione
1 Stuk / 1 Sobre / 1 Styck
1 パケット

TVT DEVICE



Undyed PROLENE* (polypropylene) non absorbable tape.
Bandelette PROLENE* (polypropylène) incolore non résorbable.
PROLENE* ungefärbt (polypropylen) nicht resorbierbarer Netzstreifen.
Nastro in PROLENE* (polipropilene) non assorbibile non colorato.
Ongekleurde PROLENE* (polypropyleen) niet resorbeerbaar band.
Cinta de PROLENE* (polipropileno) sin tenir, no absorbible.
Ofärgat, icke - resorberbart PROLENE (polypropylen) band.
無染色プロリーン* (ポリプロピレン製) 非吸収性テープ

輸入・発売元 ジョンソン・エンド・ジョンソン 株式会社
東京都江東区東陽6丁目3番2号

EC
Legal Manufacturer
ETHICON SaRL
Rue du Puits Godet 20, CH-2000
Neuchatel, Switzerland

CE 0123
Made in Switzerland

Authorized Representative • Erkende vertegenwoordiger • Représentant autorisé • Autorisierter Vertreter • Rappresentante autorizzato • Representante autorizado • Representante autorizado

ETHICON GmbH
Robert-Koch-Strasse 1
D-22851 Norderstedt
Deutschland

STERILE EO

2 Do Not Reuse/Resterilize

! See Instructions For Use

For Use Under U.S. Patent No. 5,899,909

Distributor: Europe/Japan
Direct all correspondence to your local distributor. See insert.
Adresser toute correspondance à votre distributeur local. Voir notice.
Kontaktadresse (siehe Gebrauchsanweisung)
Inviare tutta la corrispondenza al vostro distributore locale. Vedi inserto.
Richt al uw correspondentie aan uw locale distributeur. Zie de gebruiksaanwijzing.
Dirija toda la correspondencia a su distribuidor local. Lea el prospecto.
Hanvänd er till den lokala distributören i all korrespondens. Se bruksanvisning
通信はすべてあなたのローカル供給事業所あて...お願いします。 同封紙参照。

Distributor (USA):
GYNECARE
ETHICON, Inc.
a Johnson & Johnson company
Somerville, New Jersey 08876-0151

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

*Tracemark

P15508 810041.S01

GYNECARE™

+H2348100412/
+$$0106889490/R

TVT DEVICE 810041 1.1cm x 45cm (0.5in. x 18in.) LOT 889490 2006-01

78 249

(b)(4)Proprietary Information-Technical specs

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Instructions for Use of Predicate Device: TVT
(Tension-Free Vaginal Tape)
by Ethicon Inc.

(GB) (USA) Tension-free Vaginal Tape (TVT) System — Instructions for Use

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

Please read all information carefully.
Failure to properly follow instructions may result in improper functioning of the device and lead to injury.

Important:
This package insert is designed to provide instructions for use of the Tension-free Vaginal Tape single use device, reusable introducer and reusable rigid catheter guide. **It is not a comprehensive reference to surgical technique for correcting SUI (Stress Urinary Incontinence).** The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence. These instructions are recommended for general use of the device. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION *(System)*
TVT consists of the following:

- TVT Single-Use Device, provided sterile (available separately)
- TVT Reusable Introducer, provided non-sterile (available separately)
- TVT Reusable Rigid Catheter Guide, provided non-sterile (available separately).

TVT DEVICE
The TVT device is a sterile single use device, consisting of one piece of undyed PROLENE* polypropylene mesh tape) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars.

PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE* polypropylene nonabsorbable surgical suture. The mesh is approximately 0.027 inches (0.7mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE mesh is knitted by a process which interlinks each fiber junction and which provides for elasticity in both directions. This bi-directional elastic property allows adaptation to various stresses encountered in the body.

TVT INTRODUCER
The TVT introducer is provided non-sterile and is reusable. The introducer is made of stainless steel. It consists of two parts, a handle and an inserted threaded metal shaft. The introducer is intended to facilitate the passage of the TVT device from the vagina to the abdominal skin. It is connected and fixed to the needle, via the threaded end of the shaft, prior to inserting the needle with the tape.

TVT RIGID CATHETER GUIDE
The TVT rigid catheter guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter **(recommended size 18 French)** positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS
The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

25

Instructions for Use of Predicate Device: TVT (Tension-Free Vaginal Tape) by Ethicon Inc.

INSTRUCTIONS FOR USE

The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia. The extent of dissection is minimal, i.e. a vaginal midline entry with a small paraurethral dissection to initially position the needle and two suprapubic skin incisions.

Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision about 1.5 cm long starting approximately 1.0 cm from the outer urethral meatus. This incision will cover the mid-urethral zone and will allow for subsequent passage of the sling (tape). With a small pair of blunt scissors, two small paraurethral dissections (approximately 0.5 cm) are made so that the tip of the needle can then be introduced into the paraurethral dissection. Then, two abdominal skin incisions of 0.5 - 1 cm are made, one on each side of the midline just above the symphysis not more than 4-5 cm apart. Incision placement and needle passage near the midline and close to the back of the pubic bone are important to avoid anatomic structures in the inguinal area and lateral pelvic sidewall.

The TVT rigid catheter guide is inserted into the channel of the Foley catheter (18 French). The handle of the guide is bent around the catheter, proximal to its widening. The purpose of the guide is to move the bladder neck and urethra away from where the tip of the needle will pass into the retropubic space. Via use of the Foley catheter and the rigid catheter guide, the urethra and bladder are moved contralaterally to the side of the needle passage. During this maneuver, **the bladder should be empty**. The threaded end of the introducer is screwed into the end of one of the needles.

Using the introducer, the needle is passed paraurethrally, penetrating the urogenital diaphragm. Insertion and passage are controlled by using the long or index finger in the vagina under the vaginal wall on the ipsilateral side and fingertip control on the pelvic rim. The curved part of the needle should rest in the palm of the "vaginal" hand. If you are right handed this means that the left hand generally is the one to be used for needle guidance. With the other hand grip the handle of the introducer gently. Now introduce the needle tip into the retropubic space. Once again observe that this should be done by the palm of the vaginal hand and with the needle tip horizontally i.e. in the frontal plane. After passage of the urogenital diaphragm you will feel that the resistance is significantly reduced. Immediately aim the tip of the needle towards the abdominal midline and lower the handle of the introducer thereby pressing the tip of the needle against the back of the pubic bone. Now, move the needle up upwards to the abdominal skin incision, keeping in close contact with the pubic bone all the way.

When the needle tip has reached the abdominal incision cystoscopy is performed to confirm bladder integrity. The bladder must be emptied after the first cystoscopy. The procedure is then repeated on the other side. The needles are then pulled upward to bring the tape (sling) loosely, i.e. without tension, under the midurethra. Cut the tape close to the needles. Now adjust the tape so that leakage is limited to no more than one or two drops. Use patient feedback i.e. coughing with a full bladder (approximately 300ml) and keep the vaginal incision temporarily closed by a gentle grip with small forceps. The plastic sheaths that surround the tape are then removed. **To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheaths.** Premature removal of the sheath may make subsequent adjustments difficult. After proper adjustment of the tape, close the vaginal incision. The abdominal ends of the tape are then cut and left in subcutis. Do not suture them. Suture the skin incisions. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty the bladder 2-3 hours after the operation.

Instructions for Use of Predicate Device: TVT (Tension-Free Vaginal Tape) by Ethicon Inc.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- **Do not use TVT procedure for patients who are on anti-coagulation therapy.**
- **Do not use TVT procedure for patients who have a urinary tract infection.**
- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Post operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

Instructions for Use of Predicate Device: TVT (Tension-Free Vaginal Tape) by Ethicon Inc.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

INSTRUCTIONS FOR CLEANING REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

To ensure the reliability and functionality of the TVT Introducer and TVT Rigid Catheter Guide, clean the instrument before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instrument.

Prior to cleaning, the TVT introducer should be separated into its two component parts (handle and threaded shaft). The introducer is reassembled after cleaning and before sterilization.

Manual method

1. Soak the instrument components in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument components in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument components may be treated with instrument lubricant.

Automated Method:

1. Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below.

- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176°F (80°C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176°F (80°C) – 2 minutes
- Dry 194°F (93°C) – 10 minutes

STERILIZATION RECOMMENDATIONS FOR REUSABLE INSTRUMENTS (TVT Introducer and TVT Rigid Catheter Guide)

The TVT Introducer and Rigid Catheter Guide are supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

Instructions for Use of Predicate Device: TVT (Tension-Free Vaginal Tape) by Ethicon Inc.

INSTRUMENT MAINTENANCE

- TVT Introducer

Before each use, inspect the threaded parts of the inner shaft.

- TVT Rigid Catheter Guide

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

HOW SUPPLIED

The TVT device is provided sterile ethylene oxide) for single use. Do not re-sterilize. Do not use if package is opened or damaged. Discard opened, unused devices.

The reusable TVT introducer and TVT rigid catheter guide accessories are supplied separately, and are non-sterile. These accessories are to be cleaned and sterilized prior to each use as described above.

STORAGE

Recommended storage conditions for the TVT single use device are below 25°C, away from moisture and direct heat. Do not use after expiry date.

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

EC
Legal Manufacturer
ETHICON SaRL
Rue du Puits Godet 20, CH-2000
Neuchatel, Switzerland

Distributor (Europe):
ETHICON Ltd
Bankhead Avenue
Edinburgh, EH11 4HE
United Kingdom

Distributor (USA):
Gynecare
a division of Ethicon, Inc.
a Johnson & Johnson Company
Somerville, NJ
08876-0151

Premarket Notification for T-Sling

Instructions for Use of Predicate Device: IVS TUNNELLER*

(Intra-Vaginal Sling Placement Instrument)

United States Surgical a division of Tyco Healthcare Group

IVS TUNNELLER*

Intra-Vaginal Sling Placement Instrument

Dispositif de Positionnement de Fronde Intra-vaginale

Intravaginales Instrument zur Schlingenplazierung

Disposivito di Posizionamento dello Sling Intravaginale

Instrumento de Colocasión del Suspensorlo Intravaginal

Instrumento para Colocação de Sling Intravaginal

Instrument voor het Aanbrengen van een Intra-vaginaal Lusverband

Instrument för Insättning av Intravaginal Slynga

Instrument til Placering af Intravaginal Slynge

Εματτιμενσισαϊσεν Καννατττιμεν Σιϳοιτυσινστρυμεντττι

Εργαλειου Ενδοκολπικής Ανάτασης του Αυχένος της Ουρήθρας

tyco / Healthcare / United States Surgical

CE 0344 STERILE EO

- Do not use if unit package is opened or damaged. Do not resterilize. Ne pas utiliser si l'emballage est ouvert ou endommagé. Ne pas restériliser. Nicht verwenden, bei geöffneter oder beschädigter Einzelverpackung. Gerät nicht erneut sterilisieren. • Non utilizzare se la confezione individuale è aperta o danneggiata. Non risterilizzare. • No utilizar si el paquete está abierto o dañado. No reesterilizar. • Får ej användas om innerlåsförpackningen är öppnad eller skadad. Får ej steriliseras om. • Niet gebruiken wanneer de stuksverpakking geopend of beschadigd is. Niet hersteriliseren. • Må ikke brukes hvis emballasjen er åpnet eller beskadiget. Må ikke gensteriliseres. • Älä käytä, jos tuotepakkaus on auki tai vahingoittunut. Valmista ei saa sterilisoida uudestaan. • Να μην χρησιμοποιείτε εάν έχει ανοιχθεί η συσκευασία ή έχει υποστεί ζημιά. Μην επαναποστειρώνετε.

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

*Trademark

Distributed in United States by United States Surgical a division of Tyco Healthcare Group LP

MANUFACTURER: EUROPEAN CUSTOM MANUFACTURING B.V., CUSTOM 54 5422 VZ GEMERT
EC REP: TYCO HEALTHCARE UK LTD, GOSPORT, PO13 0AS, UK
0344 [illegible]

LP[illegible]

English

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT*

This booklet is designed to assist in using the IVS Tunneller* Intra-Vaginal Sling Placement Instrument as a reference to surgical techniques.

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

INDICATIONS

The IVS Tunneller* Intra-Vaginal Sling Placement Instrument is intended to be used in females to position a polypropylene mesh tape for the treatment of Genuine Stress Urinary Incontinence (SUI) (mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency) and vaginal vault prolapse.

EFFECTS

The IVS Tunneller* Instrument is sterilized with Ethylene Oxide. The IVS Tunneller* Instrument is sterile and non-pyrogenic prior to opening of the packaging under the expiration date mentioned on the product label, unless the packaging is damaged or previously opened. The IVS Tunneller* Instrument is for single use only. Do not reuse or resterilize.

The IVS Tunneller* Instrument is used during intra-vaginal slingplasty and related procedures for the treatment of stress incontinence by repairing the anterior compartment of the vagina.

Specifically, a tension free polypropylene mesh tape is used to support the pubo-urethral ligament (PU) of the urethra while also tightening the vaginal hammock.

The IVS Tunneller* Instrument is composed of three components: a stainless steel introducer, a polypropylene stylette and a polypropylene mesh tape.

The introducer is a 90° curved stainless steel tube with delta wing polypropylene handle which is used for the correct positioning of the polypropylene mesh tape.

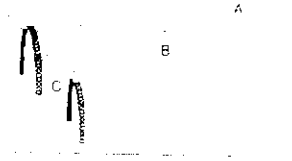
The polypropylene stylette has an eyelet for the polypropylene mesh tape threading and an atraumatic tip at the end which allows for a blunt tissue dissection to facilitate the passage of the introducer. It also acts as a pivot in the pulling of the polypropylene mesh tape through the introducer.

The SURGIPRO* mesh tape is a non-absorbable inert, sterile porous surgical mesh tape knitted from multi-filament yarns which are made from the same type of polypropylene polymer that are used to fabricate SURGIPRO* surgical sutures. Synthetic polypropylene is reported to

exert tensile strength loss indefinitely in tissue. SURGIPRO* mesh tape is knitted in such a fashion as to interconnect each multi-filament yarn and provide bi-directional elasticity. SURGIPRO* mesh tape is used to repair or reinforce defects following surgery or trauma and serves to provide additional support to such wounds during the wound healing period. Animal studies have shown that the polypropylene filaments from which this mesh tape is manufactured elicit a minimal acute inflammatory reaction in tissue which is then followed by gradual encapsulation by fibrous tissue. Ingrowth of this fibrous tissue that is permitted by the porosity of the knitted mesh tape structure.

SCHEMATIC VIEW

A: POLYPROPYLENE STYLETTE
B: STAINLESS STEEL INTRODUCER
C: POLYPROPYLENE MESH TAPE



INSTRUCTIONS FOR USE

Examine all components of the IVS Tunneller* instrument after opening the package. Do not use if the packaging of the product is damaged or if the packaging was previously opened.

MIDLINE IVS METHOD

Make single full thickness midline incision [illegible] the level of mid urethra. Use scissors to create [illegible] space on each side of the urethra, proceeding in behind pubic bone. Use blunt fingers to open a space between the ligaments behind the symphysis until bare bone is felt. Insert the IVS Tunneller* instrument. Use fingertip pressure only to slide the IVS Tunneller* instrument up the posterior surface of the pubic bone, keeping the delta wing handle horizontal at all times.

Use the polypropylene stylette to position SURGIPRO* mesh tape. Perform cystoscopy. If bladder is perforated, remove IVS Tunneller* instrument, reinsert SURGIPRO* mesh tape and keep catheter in overnight. Do not SURGIPRO* mesh tape without tension. Cut SURGIPRO* mesh tape at skin level and suture skin. Suture vaginal incision.

3 POINT METHOD

Proceed exactly as for Midline IVS Method. Then close external vaginal (EUL) and re-suture with [illegible] tension. Attach hammock to pubococcygeus (PC) without tension at level of mid urethra.

PARA-URETHRAL IVS METHOD

Make two full thickness para-urethral incisions in the Anterior Vaginal Wall to create a sub-urethral tunnel for the SURGIPRO* mesh tape. Use blunt fingers to open a space between the ligaments behind the symphysis until bare bone is felt. Insert the IVS Tunneller* instrument. Use fingertip pressure only to slide the IVS Tunneller* instrument up the posterior surface of the pubic bone, keeping the delta wing handle horizontal at all times. Use the polypropylene stylette to position SURGIPRO* mesh tape. Perform cystoscopy. If bladder is perforated, remove IVS Tunneller* instrument, reinsert SURGIPRO* mesh tape and keep catheter in overnight. Do not SURGIPRO* mesh tape without tension. Cut SURGIPRO* mesh tape at skin level and suture skin. Suture vaginal incision.

3 POINT METHOD

Proceed exactly as for Para Urethral IVS Method. Then close external vaginal (EUL) and re-suture with [illegible] without tension. Attach hammock to pubococcygeus (PC) without tension at level of mid urethra.

POSTERIOR IVS (INFRA COCCYGEAL SACROPEXY) METHOD

Prepare bowel with rectal suppositories pre-operatively. Make transverse vaginal incision 3.5 cm below hysterectomy scar. Make two 0.6 cm para rectal skin incisions, 2 cm lateral to external sphincter. Use Tunneller* instrument and introduce ischio-rectal fossa keeping head parallel to the floor. Angle tip medially to the remnants of the Sacro Spinal Ligament. Check vaginally for correct bone penetration then radially to ensure there is no rectal perforation. Use the polypropylene stylette to position SURGIPRO* mesh tape. Suture [illegible] mesh tape to under surface of upper vaginal flap (only). DO NOT suture peritoneal flap of SURGIPRO* mesh tape. Proceed to posterior colporrhaphy repair. Resect excess vaginal tissue and re-peritonise. Cut tape at skin level. If rectum is perforated, remove SURGIPRO* mesh tape and re-insert. Suture vaginal and rectal perforations.

WARNINGS

1. users should be familiar with surgical procedures and techniques involving the use of surgical mesh before employing the SURGIPRO* mesh tape in any repair procedure.
2. The user is responsible for the correct use of the IVS Tunneller* instrument.
3. Be sure that ALL hospital personnel pertaining to this procedure are made aware of the warnings and precautions about the use of the IVS Tunneller* instrument.
4. Cystoscopy must be performed during the procedure to confirm that there are no bladder or urethral perforations.
5. Following a hysterectomy, the patient should be evaluated that future pregnancies will not negate the effects of the surgical procedure and the patient may again become pregnant.
6. Patients undergoing the transvaginal sling procedure should be counseled to avoid physical strain and heavy lifting for 6 to 8 weeks post procedure or as advised by their doctor.
7. Over correction may cause temporary or permanent lower urinary obstruction.
8. Special attention should be given to patients with renal insufficiency, patients with upper urinary tract infection/obstruction and patients who are on anti-coagulation therapy.
9. Standard hospital procedure concerning maintaining sterility and preventing infections are to be followed.

ADVERSE REACTIONS

No adverse reactions are reported which are directly attributable to polypropylene fibers. While polypropylene itself remains unaffected by infection, SURGIPRO* mesh tape, as with any non-absorbable mesh tape, may exacerbate infection and lead to fistula formation and/or extrusion of the mesh tape.

CONTRAINDICATIONS

This device is not designed [illegible]

90 261

Jones, Edwena

From: Andrews, Sharon M
Sent: Thursday, June 27, 2013 2:04 PM
To: Jones, Edwena
Subject: RE: Change of Ownership of 510(k) to (b)(4)Proprietary Information

Hi Edwena,

(b)(4)Proprietary Information

Thank you.

Sharon

From: Jones, Edwena
Sent: Wednesday, June 19, 2013 11:06 AM
To: Shulman, Marjorie G.
Cc: Andrews, Sharon M
Subject: RE: Change of Ownership of 510(k) to (b)(4)

(b)(4)

Thanks
Edwena

From: Shulman, Marjorie G.
Sent: Wednesday, June 19, 2013 9:52 AM
To: Jones, Edwena
Cc: Andrews, Sharon M
Subject: FW: Change of Ownership of 510(k) to (b)(4)Proprietary Information

Hi Edwena,

(b)(4)Proprietary Information

Thanks,

Marjie

Marjorie Shulman
Director, Premarket Notification [510(k)] Program
Program Operations Staff
ODE/CDRH/FDA, WO66-1536
10903 New Hampshire Avenue

Silver Spring, MD 20993-0002
(301) 796-6572
Marjorie.Shulman@FDA.HHS.GOV

From: Andrews, Sharon M
Sent: Thursday, May 30, 2013 9:22 AM
To: Shulman, Marjorie G.; Jones, Edwena
Cc: Ivey, Nathan; Blyskun, Elaine
Subject: Change of Ownership of 510(k) to (b) [redacted]

Hi Marjie and Edwena,

(b)(4)Proprietary Information

[redacted]

Thank you.

Sharon

From: Ivey, Nathan
Sent: Tuesday, May 28, 2013 7:17 AM
To: Andrews, Sharon M
Cc: Gatski, Megan; Loyo-Berrios, Nilsa; Anderson-Smits, Colin
Subject: (b) [redacted] Change of Ownership for 510(K) database

Hi Sharon,

(b)(4)Proprietary Information

[redacted]

Sincerely,

Nathan S. Ivey, PhD | Senior Scientific Project Manager | 522 Postmarket Surveillance (PS) Studies Program | FDA/CDRH/OSB/DEPI
301.796.7033 (ofc) | **Nathan.Ivey@fda.hhs.gov**

From: (b) (6) [redacted]
Sent: Monday, May 27, 2013 11:38 AM
To: Ivey, Nathan
Cc: (b) (6) [redacted]
Subject:

Dear Nathan

(b)(4)Proprietary Information

[redacted]

Sharon M. Andrews
FDA/DRGUD/OGDB
10903 New Hampshire Avenue
WO66, Room G110
Silver Springs, MD 20993

May 27, 2013

Dear Mrs. Andrews,

I am writing you to inform the FDA that Herniamesh SRL now owns K050516 (previously owned by Caldera Medical Inc.) based on the ruling of litigation between Herniamesh and Caldera.The litigation (arbitration) case between "Herniamesh and Caldera", was settled before a final decision was made by the arbitrator. On May 22, 2009 Caldera assigned 510(k) 050516 to Herniamesh SRL as part of the settlement of the arbitration case Herniamesh S.r.l. v. Caldera Medical, Inc., ICDR Case No. 50 155 T 00318 07.

In the included document you will find the assignment of 510(K) premarket notification agreement, which is only part of the full settlement. If the FDA believes it needs a copy of the full Settlement Agreement, it can be sent to FDA but only after the payment amounts are blacked out because the Settlement contains a confidentiality provision which states the sums payable shall be kept confidential and shall not be disclosed.

If you require any additional information or explanation please let me know.

Sincerely,

(b) (6)

EXHIBIT C

ASSIGNMENT OF 510(K) PREMARKET NOTIFICATION

THIS ASSIGNMENT (this "Assignment") is made and entered into as of May 22, 2009 between Caldera Medical, Inc., with an address of 28632 Roadside Drive, Suite 260 Agoura Hills, California ("Assignor"), and Herniamesh S.r.l., with an address of Via F.lli Meliga 1/C I-10034 Chivasso (To) Italy ("Assignee").

Recitals

A. Assignor affirms, represents, and warrants that, to the best of Assignor's knowledge, it is the owner of U.S. Food and Drug Administration 510(k) Premarket Notification K050516 ("Premarket Notification K050516");

B. Assignor has agreed and contracted to assign to Assignee all of Assignor's right, title, and interest in and to Premarket Notification K050516 as provided herein; and

C. Assignee now desires Assignor to execute and deliver to Assignee this Assignment to effect the assignment of Premarket Notification K050516 to Assignee as provided herein.

Agreement

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Without representation or warranty of any kind beyond those expressly contained herein, including recitals, Assignor hereby sells, transfers, conveys, assigns, and sets over unto Assignee, its successors and assigns, Assignor's entire right, title and interest in and to Premarket Notification K050516, and all common law and statutory rights related thereto.

2. Assignor and Assignee hereby agree that this Assignment shall be deemed effective and delivered upon the date first above written.

3. Assignor agrees: (a) concurrent with execution and delivery of this Assignment, to update its Registration and Listing with the U.S. Food and Drug Administration to delete the Device Listing reference to K050516; (b) to deliver to Assignee a copy of the Assignor's regulatory files associated with K050516; and (c) to execute and deliver such instruments of sale, transfer, assignment, and confirmation as Assignee may reasonably request in order to effectuate the assignment to Assignee of all of Assignor's right, title and interest in and to Premarket Notification K050516, effective as of the date first above written.

Execution

[illegible] the [illegible] written, Assignor and Assignee have duly executed this [illegible]

[illegible] MEDICAL INC

By: [illegible]
Name: [illegible]
Title: CEO

HERNIAMESH S.R.L.

By: [illegible]
Name: [illegible]
Title: [illegible]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

January 17, 2006

From: Reviewer(s) - Name(s) DONA VEGA, M.D., Ph.D. DKK

Subject: 510(k) Number K050516/S2

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 N/A

☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) NO

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):

79 FTM - 21CFR 878.3300 - SURGICAL MESH

Review: [signature] (Branch Chief) [signature] (Branch Code) 2/3/06 (Date)

Final Review: [signature] (Division Director) 2/3/06 (Date)

4

Revised:4/2/03

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 K050516

Reviewer: Dora Vega, MD, PhD

Division/Branch: DGRND/PRSB

Device Name: T-Sling

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

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

6

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:

(b)(4)Proprietary Information

[redacted]

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

10. Explain what performance data (b)(4)Proprietary Information [redacted]

11. Explain how the performance d
not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFOR

510(K) MEMORANDUM

TO: **K050516/S002**

FROM: Dora Vega, M.D., Ph.D.,
ODE / DGRND
Plastic and Reconstructive Surgery Devices Branch (HFZ-410) 1 Ehrlich 2/3

DATE: January 18, 2006

BDB 2/3/06

SUBJ: T-Sling - Surgical Mesh

CONTACT: Marla Kengen, Project Leader
Caldera Medical, 28632 Roadside Drive, Suite 260
Agoura Hill, CA 91301
Ph: (866) 422-5337 – Fax: (818) 879-6556

Procode: 79 FTM
Class: II
Regulation Number: 878.3300
Regulation Name: Surgical Mesh

(b) (5)

[redacted]

(b)(4)Proprietary Information

[redacted]

REVIEW:

(b)(4)Proprietary Information

[redacted]

8

(b)(4)Proprietary Information

[redacted]

1. **Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

(b)(4)Proprietary Information

[redacted]

Predicate device(s)

Herniamesh T-Sling, K020652: "Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency."

Ethicon TVT, K012628: "Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency."

(*)**Tyco Healthcare IVS Tunneller**: "Intended to be used in females to position a polypropylene mesh tape for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, *and vaginal vault prolapse*."

Discussion of whether the intended use/indications are the same

(b)(4)Proprietary Information

[redacted]

2. **Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device and Predicate(s)**

(b)(4)Proprietary Information

[redacted]

3. **Comparative Data (in vitro, animal and/or clinical)**

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

Effectiveness Data – Subject Device

(b)(4)Proprietary Information

Effectiveness Data - Predicate Device(s)

(b)(4)Proprietary Information

Discussion of whether the data demonstrate that the subject device is as safe and effective as the predicate(s)

(b)(4)Proprietary Information

Risk Analysis

(b)(4)Proprietary Information

4. **Does the product contain drugs or biologicals?**
The subject device does not contain drugs or biologicals.

5. **Sterilization:** (b)(4)Proprietary Information

6. Packaging

(b)(4)Proprietary Information

7. Labeling

(b)(4)Proprietary Information

8. Claims

(b)(4)Proprietary Information

9. Has sponsor provided all administrative requirements? Yes

(b)(4)Proprietary Information

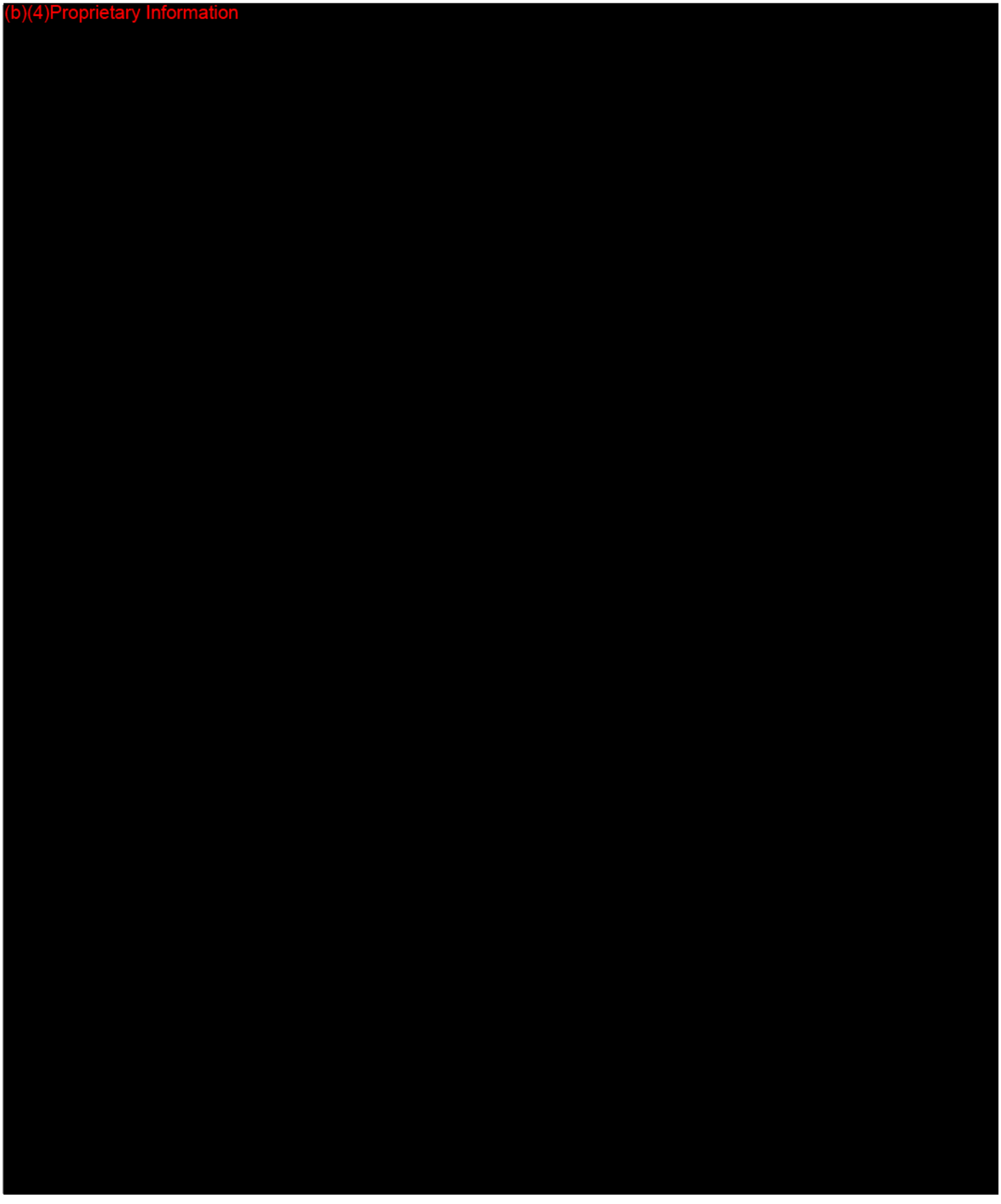
10. Analysis of the Equivalence of the Subject and Predicate(s)

(b)(4)Proprietary Information

(b)(4)Propri Deficiencies and Sponsors Response

(b)(4)Proprietary Information

(b)(4)Proprietary Information



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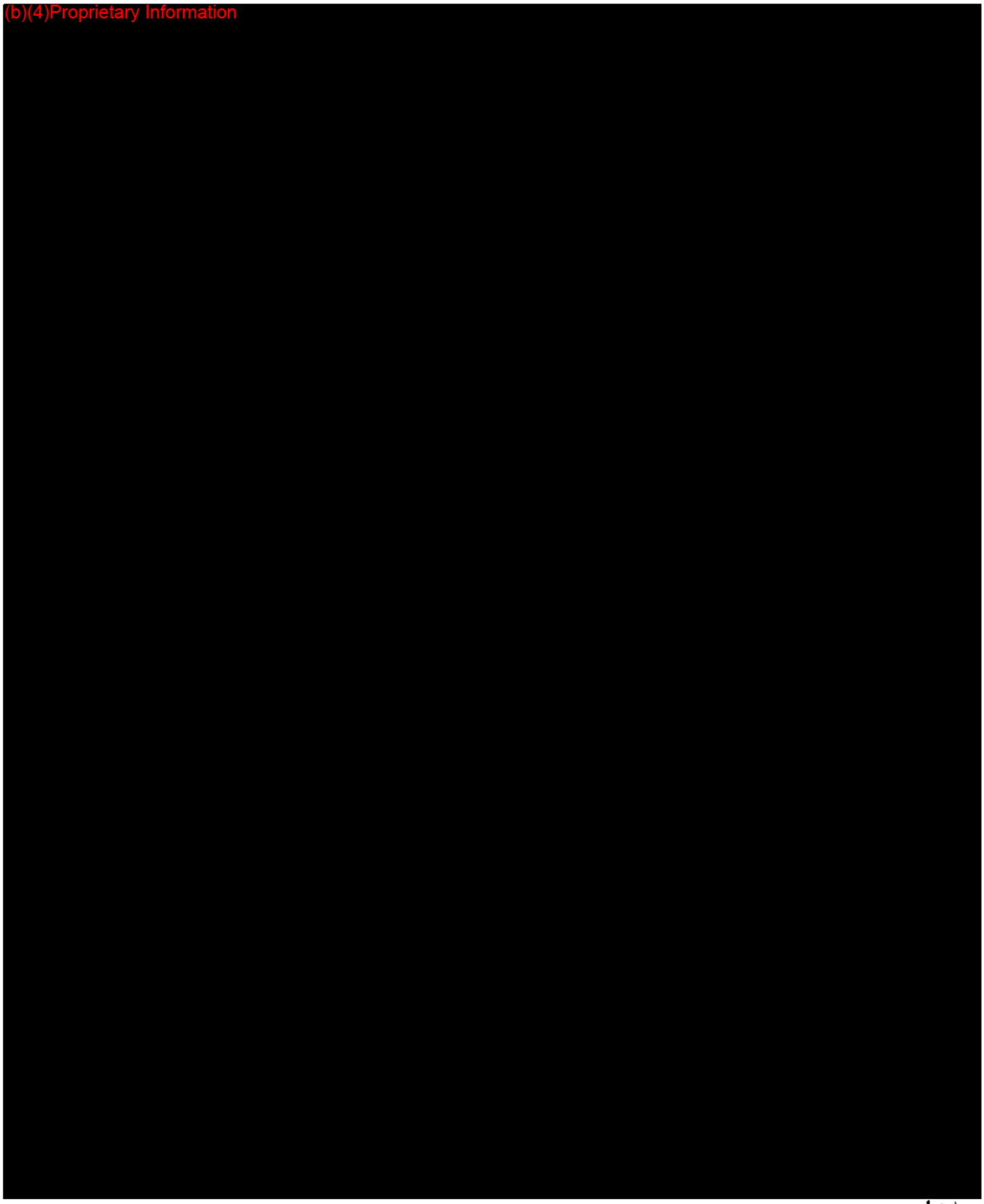

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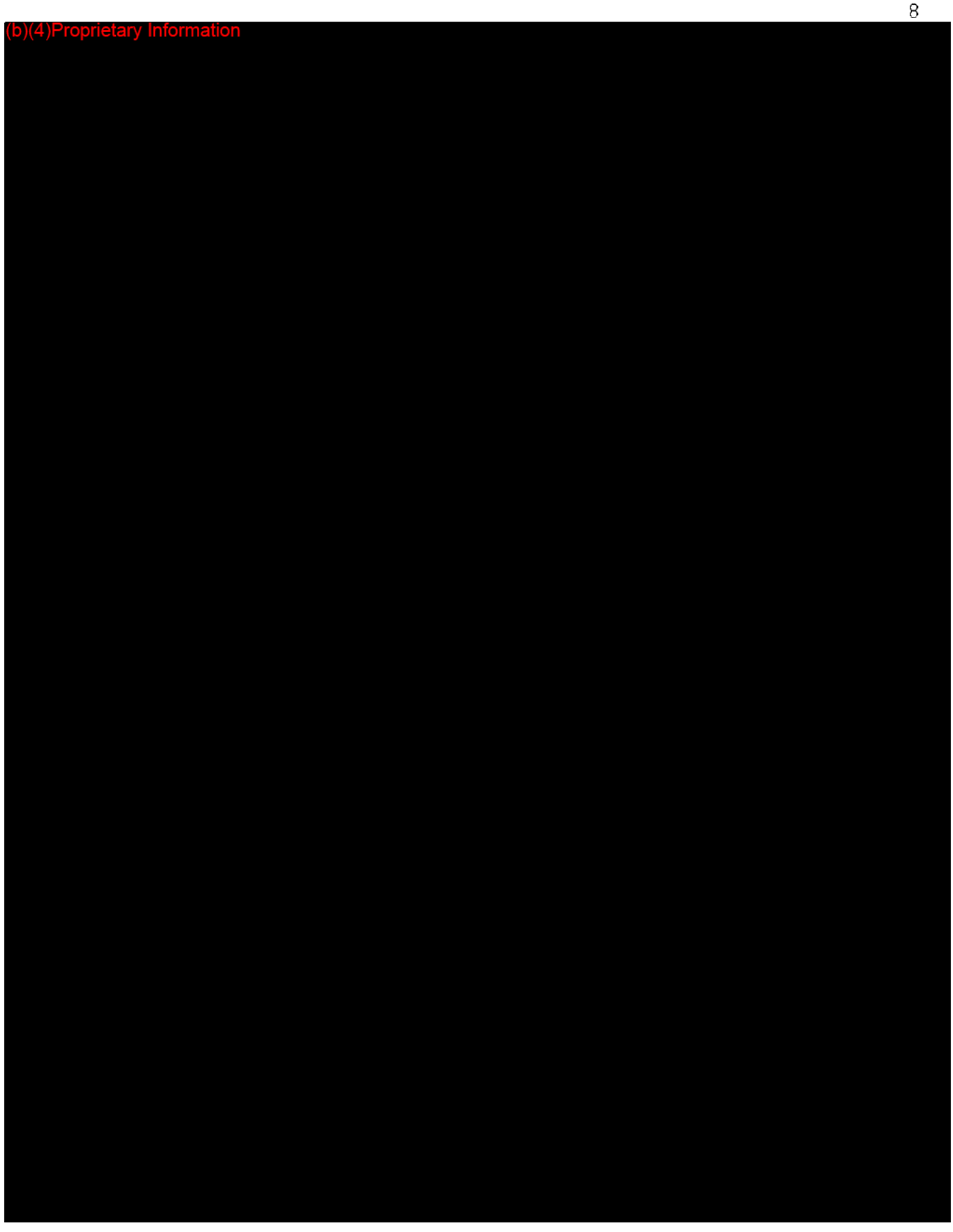

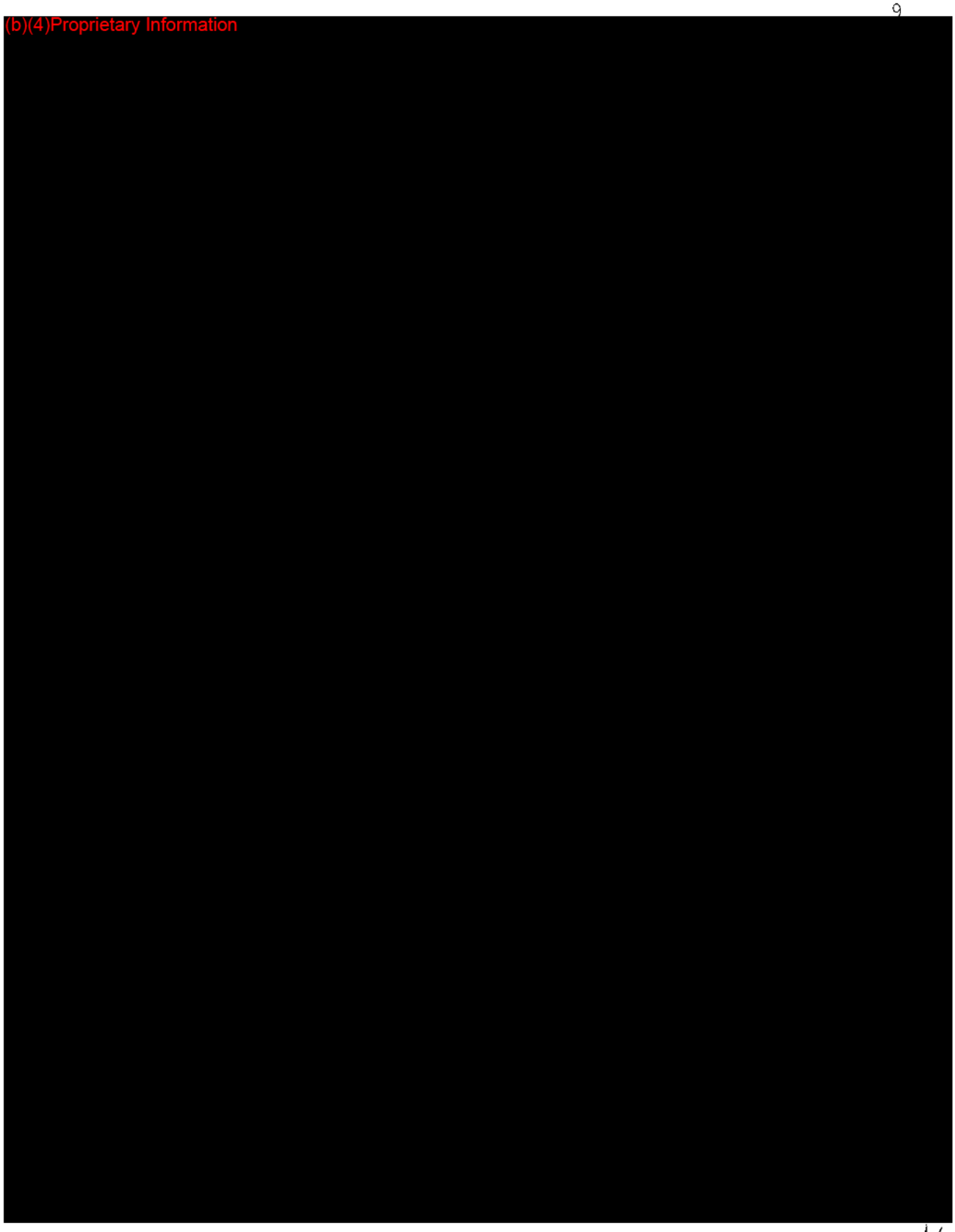

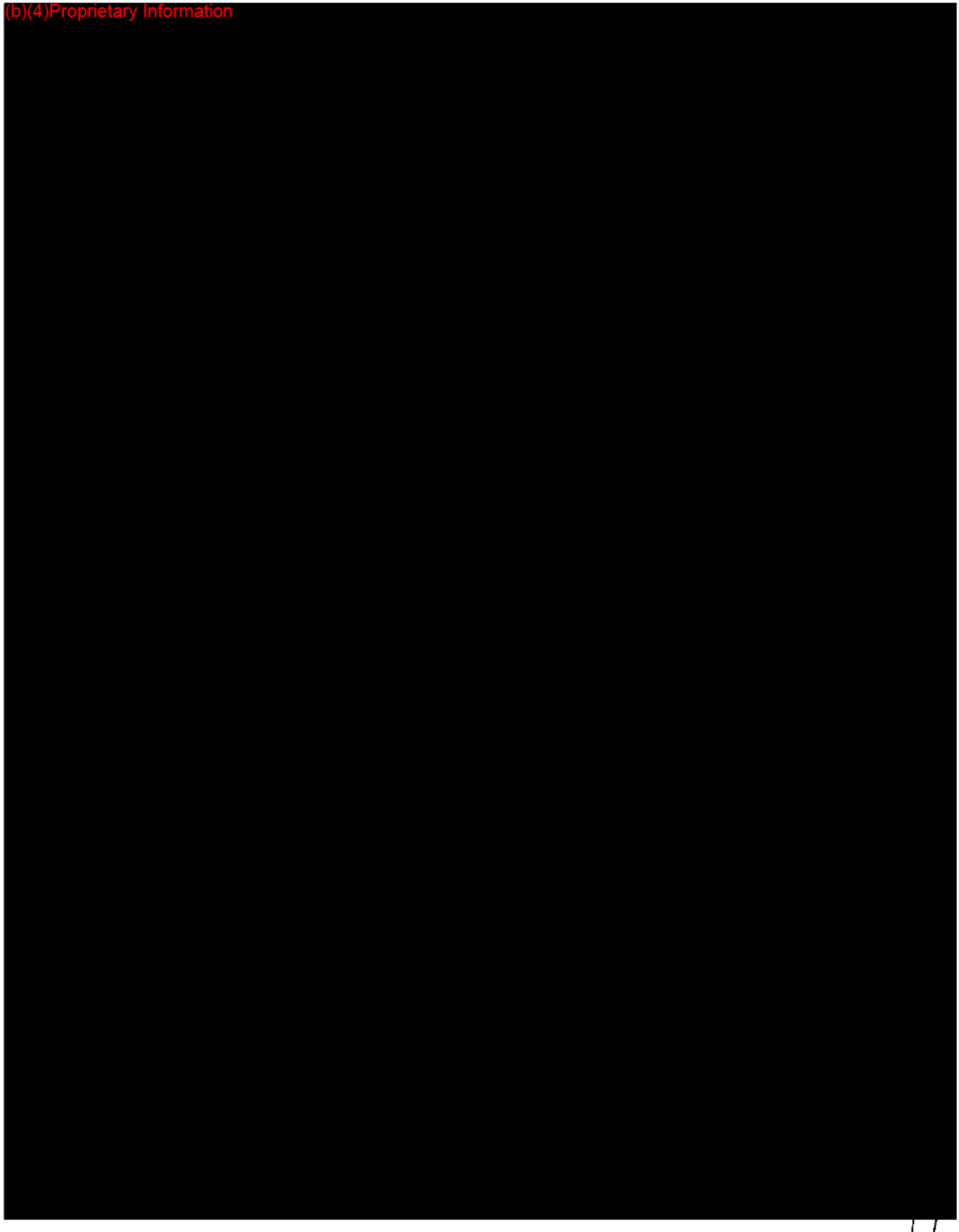

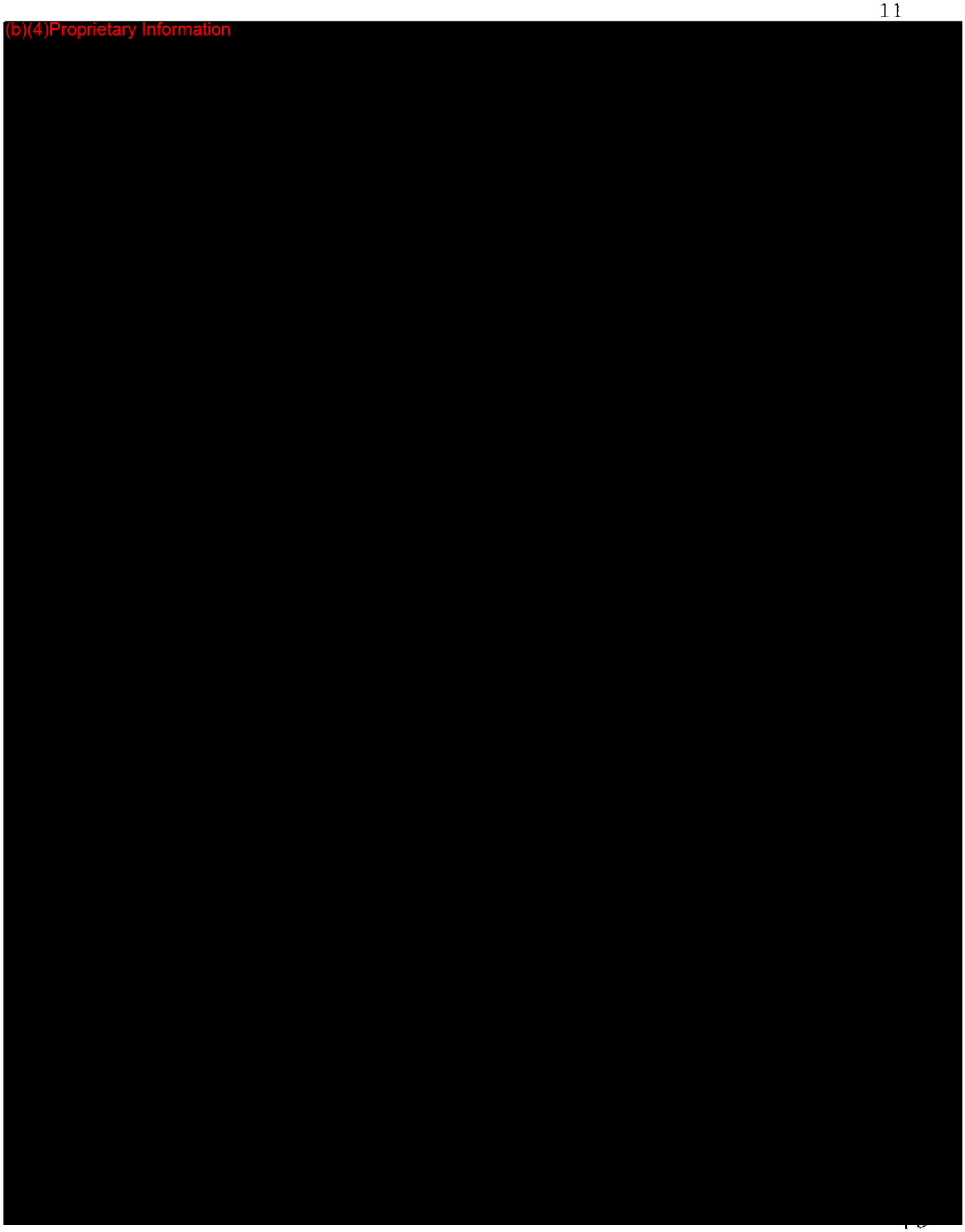

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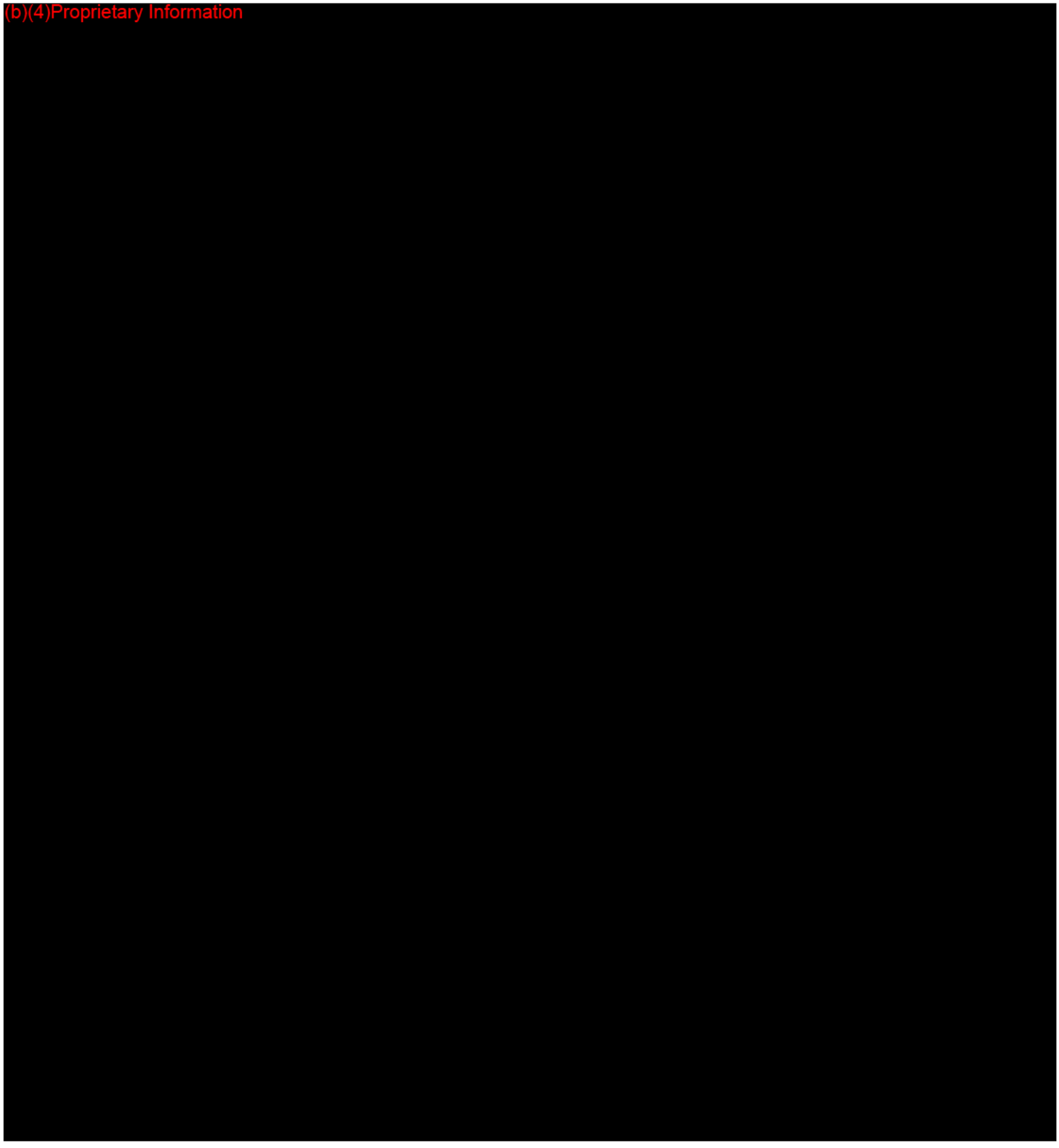


Dora Vega., M.D., Ph.D.
Medical Officer
Division of General, Restorative,
and Neurological Devices
Plastic and Reconstructive Surgery Devices Branch

Date: January 18, 2006

CALDERA MEDICAL

January 23, 2005

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

Re: K050516
T-Sling
Reviewer: Dr. Dora Vega

Dear Dr. Vega:

(b)(4)Proprietary Information

[redacted]

Regards,

Marla Kengen

Marla Kengen
Project Leader

CALDERA MEDICAL

January 19, 2005

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

Re: K050516/S001
T-Sling

Dear FDA Reviewer:

The attached document is in response to your request for additional information regarding the supplemental responses for two of the deficiencies noted in your letter of June 22, 2005 regarding Caldera Medical, Inc. T-Sling K050516.

The additional information attached is in regards to supplemental responses #10 b. & c.

After review of this additional information, if you have any questions please contact me at 818-879-6555.

Regards,

Marla Kengen

Marla Kengen
Project Leader

22

(b)(4)Proprietary Information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

JUNE 23, 2005

From: Reviewer(s) - Name(s) DONA VEGA, MD., PhD.

Subject: 510(k) Number K050516/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) No

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 days

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

79 FTM - 21 CFR 878.3300 - SURGICAL MESH.

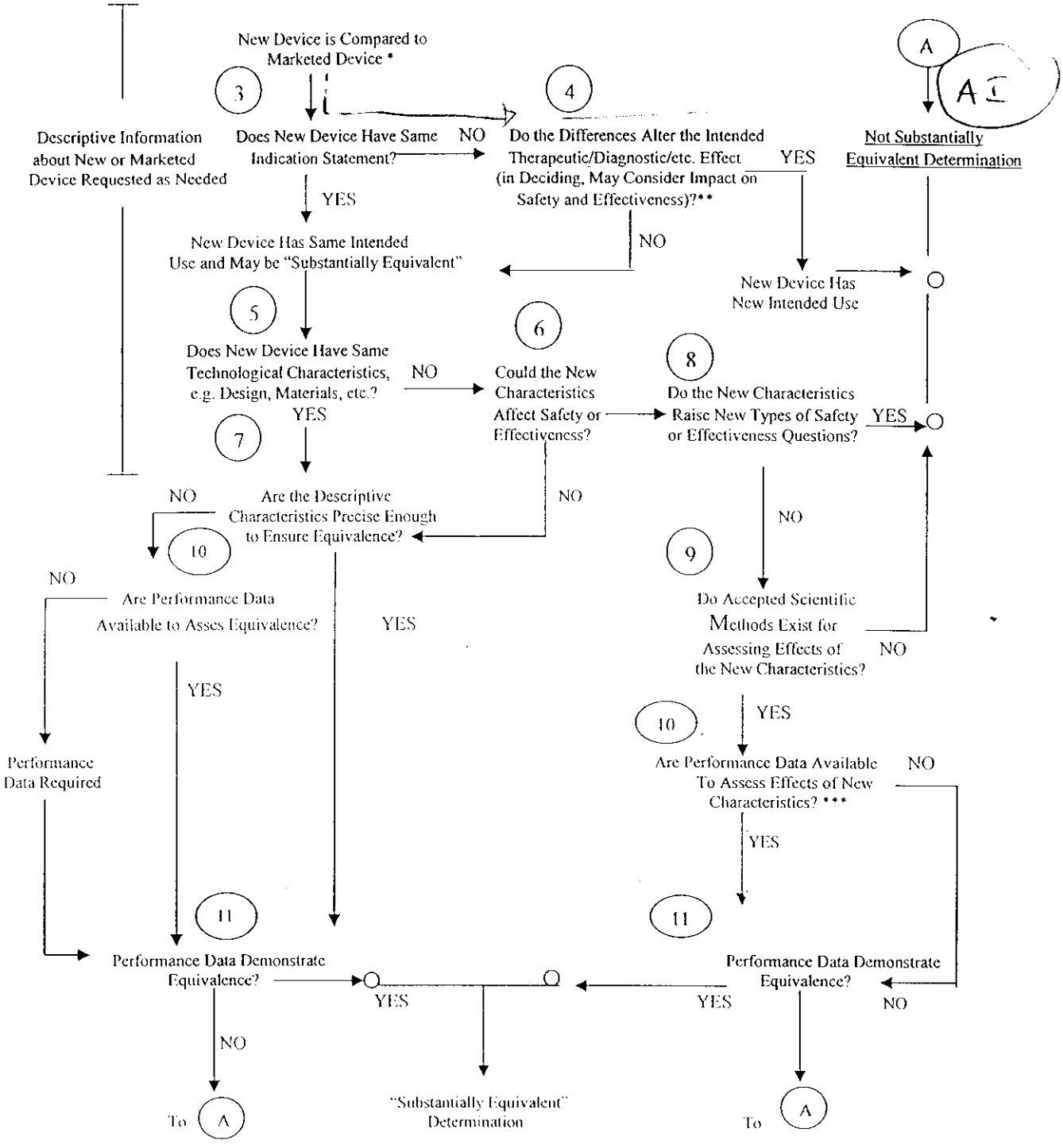
Review: [signature] (Branch Chief) PRSB (Branch Code) 6/23/05 (Date)

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

136

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.

137

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.		

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 050616/S001

Reviewer: DORA VEGA, MD, PhD.

Division/Branch: DGND - PRSB.

Device Name: T-SWING - SURGICAL MASK.

Product To Which Compared (510(K) Number If Known): K02652

	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?	✓ (UNCLEAR IFU COMPARED W/ PREDICATE).		If YES = Stop NE (AI)
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

510(K) MEMORANDUM

TO: **K050516/S001**

FROM: Dora Vega, M.D., Ph.D.,
ODE / DGRND
Plastic and Reconstructive Surgery Devices Branch (HFZ-410)

DATE: June 21, 2005

SUBJ: T-Sling - Surgical Mesh

CONTACT: Marla Kengen, Project Leader
Caldera Medical, 28632 Roadside Drive, Suite 260
Agoura Hill, CA 91301
Ph: (866) 422-5337 – Fax: (818) 879-6556

Procode: 79 FTM
Class: II
Regulation Number: 878.3300
Regulation Name: Surgical Mesh -

(b) (5)

[redacted]

REVIEW:

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

[redacted]

Device Description: T-Sling is an implantable polypropylene (non-absorbable), and polydioxanone (bioabsorbable polymer) mesh. It is unclear the device dimensions) that will be available for marketing (see listing of deficiencies.) The device is provided sterile by ETO similarly to the predicates in the application, and labeled "For a Single Use Only."

1. **Comparison of the Intended Use/Indications of the Subject Device and Predicate(s)**

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

2. **Comparison of the Technological Characteristics (Design, Materials, Sizes, Shapes, etc.) of the Subject Device and Predicate(s)**

(b)(4)Proprietary Information

3. **Comparative Data (in vitro, animal and/or clinical)**

(b)(4)Proprietary Information

(b)(4)Proprietary Information

[redacted]

Risk Analysis

(b)(4)Proprietary Information

[redacted]

4. **Does the product contain drugs or biologicals?**
The subject device does not contain drugs or biologicals.

5. **Sterilization:** (b)(4)Proprietary Information

[redacted]

6. Packaging

(b)(4)Proprietary Information

[redacted]

7. Labeling

(b)(4)Proprietary Information

[redacted]

8. Claims

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information

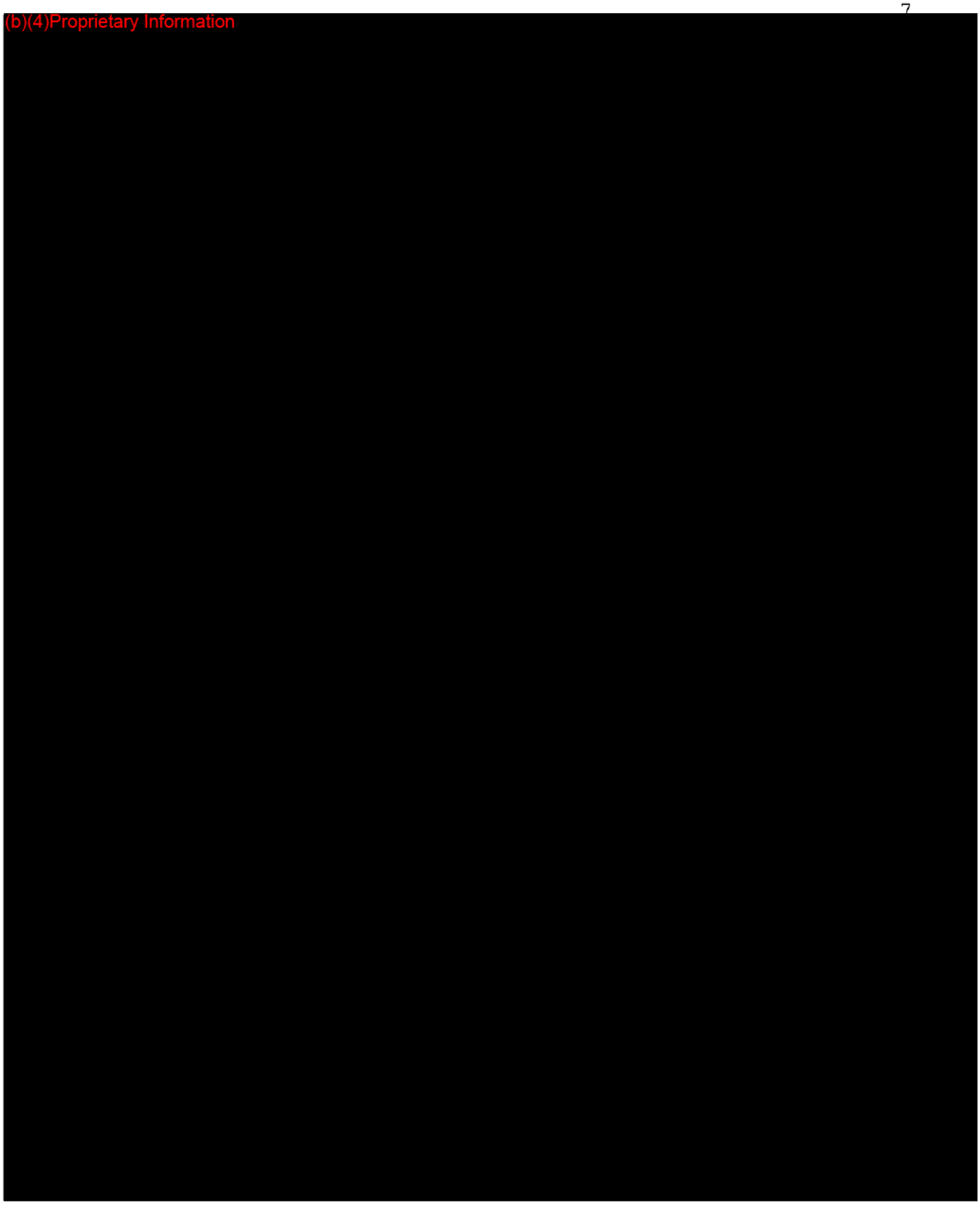
[redacted]

10. Analysis of the Equivalence of the Subject and Predicate(s)

(b)(4)Proprietary Information

[redacted]

(b)(4)Proprietary Information



(b)(4)Proprietary Information

[redacted]

Dora Vega., M.D., Ph.D.
Medical Officer
Division of General, Restorative,
and Neurological Devices

Date: June 22, 2005

Plastic and Reconstructive Surgery Devices Branch

Vega, Dora

From: Vega, Dora
Sent: Monday, June 20, 2005 12:38 PM
Hill, Ayanna Y
Cc: Hudson, Peter
Subject: K050516 - T-Sling - Caldera Medical

Ayanna,

(b) (5)

[redacted]

Dora.

150

Vega, Dora

From: Hill, Ayanna Y
Sent: Monday, June 20, 2005 2:23 PM
To: Vega, Dora
Cc: Hudson, Peter; Warfield, Diana L.
Subject: RE: K050516 - T-Sling - Caldera Medical

(b) (5) [redacted]

Thanks,
Ayanna

-----Original Message-----
From: Vega, Dora
Sent: Monday, June 20, 2005 12:38 PM
To: Hill, Ayanna Y
Cc: Hudson, Peter
Subject: K050516 - T-Sling - Caldera Medical

Ayanna,

(b) (5) [redacted]

Dora.

151

Vega, Dora

From: Hill, Ayanna Y
Sent: Monday, June 20, 2005 4:19 PM
: Vega, Dora
Cc: Hudson, Peter; Mann, Eric A; Provost, Miriam; 'marla@calderamedical.com'
Subject: K050516-T-Sling

Importance: High

(b)(4)Proprietary Information

[redacted]

Thanks,

(T Ayanna Y. Hill
Project Manager
Plastic and Reconstructive Surgery
Devices Branch
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
(301) 594-3090 Ext. 132

152

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

MARCH 17, 2005

From: Reviewer(s) - Name(s) DENA VEGA, MD, PhD

Subject: 510(k) Number K050516

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

- ☐ Refused to accept.
- ☑ Requires additional information (other than refuse to accept). ON HOLD
- ☐ 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 days

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

21 CFR 878.3300 – SURGICAL MESH

CLASS II –

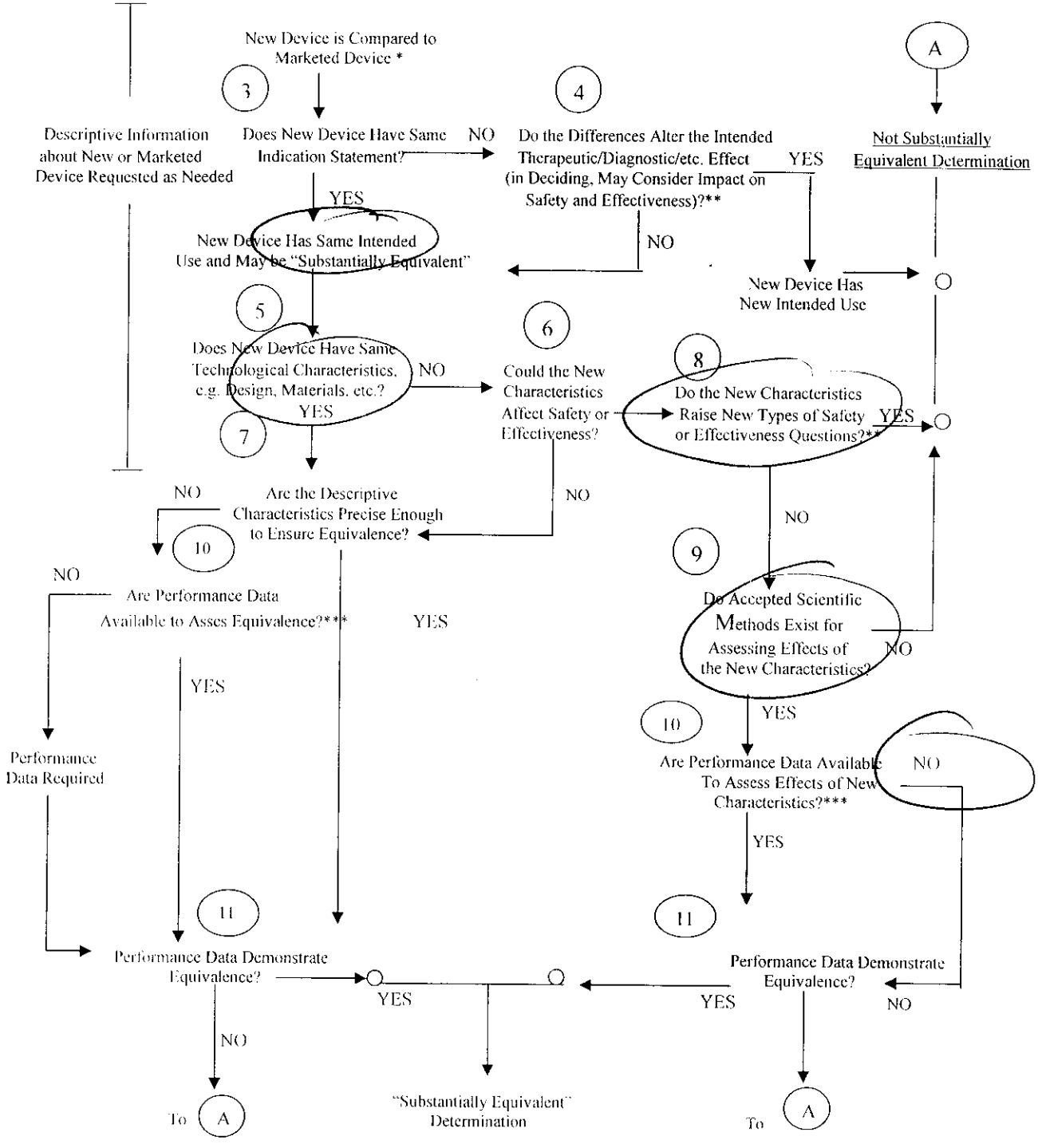
Review: Steph Church (Branch Chief) PRSB (Branch Code) 5/18/05 (Date)

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

Revised:4/2/03

158

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.

159

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?		N/A
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.	N/A	
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	

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 050516

Reviewer: DONA VEGA, MD, PhD

Division/Branch: DGIWD - PRSB

Device Name: T-SLING

Product To Which Compared (510(K) Number If Known): K010035 (I.V.S TUNNELLER)
K012628 (GYNECARE TENSION FREE TVT)

	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

510(K) MEMORANDUM

TO: **K050516**

FROM: Dora Vega, M.D., Ph.D.
ODE / DGRND
Plastic and Reconstructive Surgery Devices Branch, HFZ-410

DATE: March18, 2005

SUBJ: T-Sling - S
PROD CLASSIF: 21 CFR 878.3300 – Surgical Mesh – Class II

CONTACT: Marla Kengen
Caldera Medical, Inc.
28632 Roadside Drive, Suite 260
Agoura Hills, CA 91301
Ph: (866) 422-5337

(b) (5)

[redacted]

Dora Vega, M.D., Ph.D.
Division of General, Reconstructive,
and Neurological Devices (HFZ-410)
Plastic and Reconstructive Surgery Devices Branch

Date: March 18, 2005.

162

Vega, Dora

From: Vega, Dora
Sent: Thursday, March 17, 2005 11:51 AM
To: Hill, Ayanna Y
Zimliki, Charles L* (CDRH)
Subject: RE: K050516-T Sling

(b)(4)Proprietary Information

[redacted]

Regards, Dora.

-----Original Message-----
From: Hill, Ayanna Y
Sent: Thursday, March 17, 2005 11:36 AM
To: 'marla@calderamedical.com'
Cc: Zimliki, Charles L* (CDRH); Vega, Dora
Subject: K050516-T Sling
Importance: High

(b)(4)Proprietary Information

[redacted]

Thanks,

Ayanna Y. Hill
Project Manager
Plastic and Reconstructive Surgery
Devices Branch
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
(301) 594-3090 Ext. 132

163

Vega, Dora

From: Hill, Ayanna Y
Sent: Friday, March 11, 2005 4:02 PM
To: 'marla@calderamedical.com'
Vega, Dora
Subject: K050516-T-Sling

(b)(4)Proprietary Information

[redacted]

Ayanna Y. Hill
Project Manager
Plastic and Reconstructive Surgery
Devices Branch
Division of General, Restorative,
& Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
(301) 827-5[illegible] Ext. 1[illegible]2
(301) 827-4350(F)

164

Vega, Dora

From: Hill, Ayanna Y
Sent: Wednesday, March 16, 2005 2:59 PM
To: Zimliki, Charles L* (CDRH)
Cc: Vega, Dora
Subject: RE: [redacted] (b)(4)P

(b)(4)Propri [redacted]

Thanks,
Ayanna

(b)(4)Pr [redacted]

Ayanna

-----Original Message-----
From: Zimliki, Charles L* (CDRH)
Sent: Wednesday, March 16, 2005 2:57 PM
To: Hill, Ayanna Y
Subject: (b) [redacted]

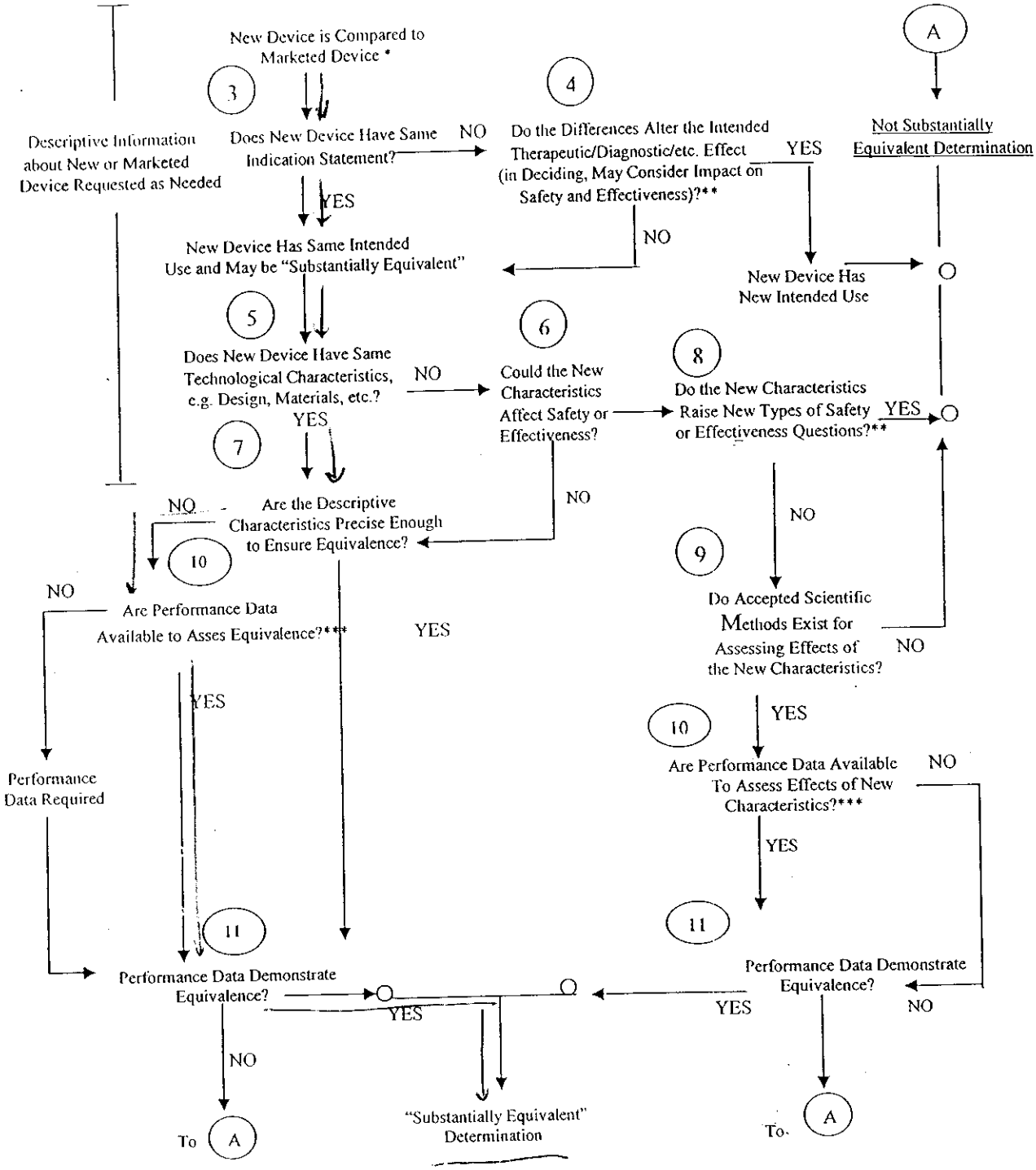
Ayanna,
(b)(4)Pro [redacted]
Chip

(b)(4)Proprietary Information [redacted]

Charles Zimliki, Ph.D.
Biomedical Engineer
FDA/CDRH/ODE/DGRND/PRSB

165

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.

5

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 20, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

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

153

April 7, 2005

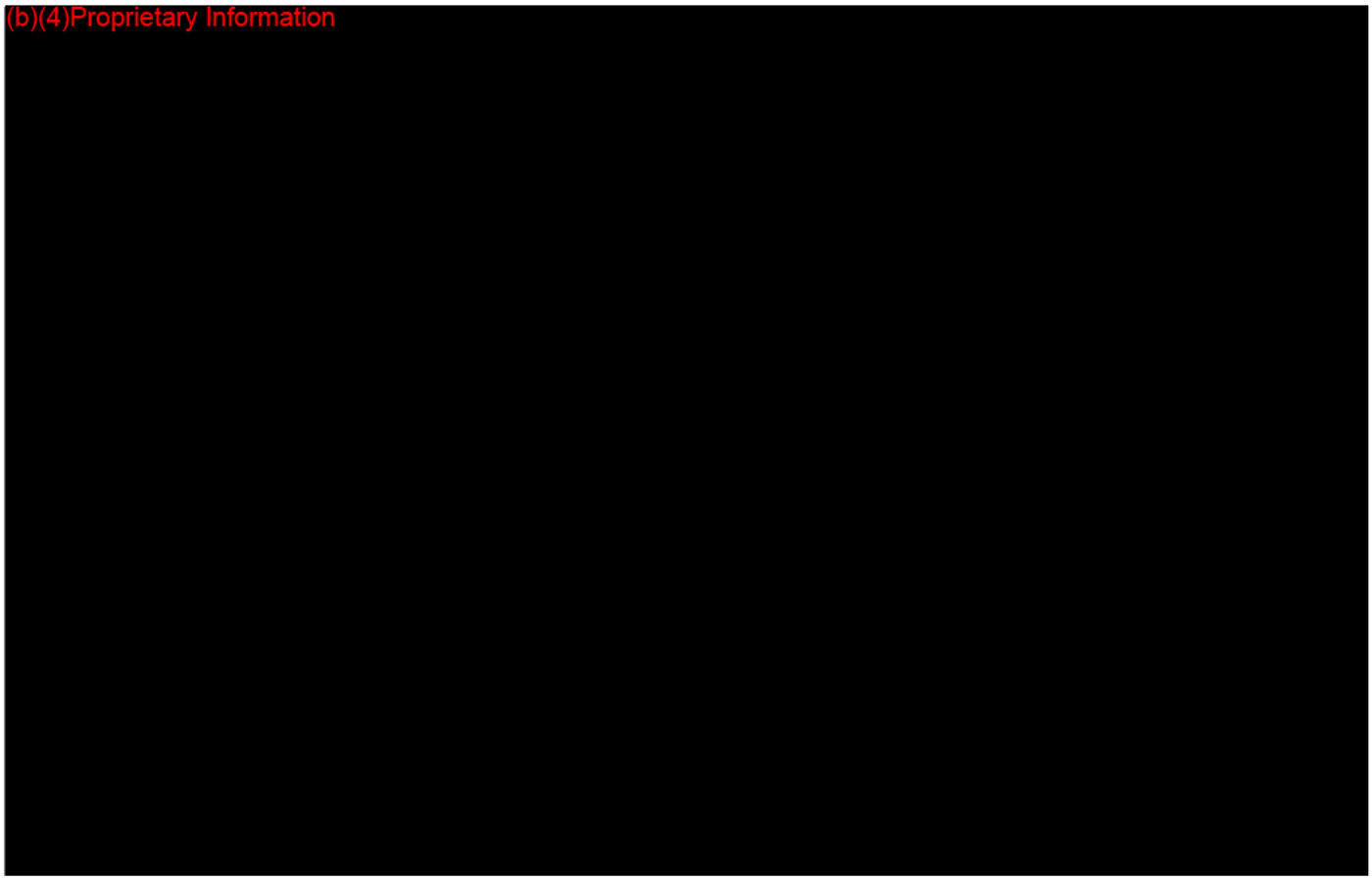
K050516/ 5 1

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockwille, MD 20850
ATTN: DORA VEGA

REFERENCE: 510(K) NUMBER: K050516
PRODUCT: T-SLING

Dear Ms. Vega:

(b)(4)Proprietary Information



Regards,

Marla Kengen
Project Leader
Attachment

154

Premarket Notification for T-Sling

AMENDMENT – April 7, 2005

Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

Feature	T-Sling	Herniamesh T-Sling	Ethicon TVT	Tyco Healthcare IVS Tunneller
510(k) No.	K050516	K020652	K012628	K010035
Classification	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh
Indication	(b)(4)Proprietary Information-draft	Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency	Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency	Intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse
Product Design	(b)(4)Proprietary Information	Pre-shaped Duel-component mesh Polypropylene and bioabsorbable polymer	Pre-shaped Polypropylene mesh	Pre-shaped Polypropylene mesh
Materials	(b)(4)Proprietary Information	Polypropylene & Polydioxanone (Bioabsorbable Polymer)	Polypropylene	Polypropylene
Sterilization	EtO	EtO	EtO	EtO
Packaging	(b)(4)Proprietary Information	Tyvek pouch with outer heat sealed foil pouch	PVC tray with Tyvek back	Substantially Equivalent
Size		2cm x 15cm	1.1cm x 45cm	Substantially Equivalent

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 19, 2005

CALDERA MEDICAL, INC.
28632 ROADSIDE DR., SUITE 260
AGOURA HILLS, CA 91301
ATTN: MARLA KENGEN

510(k) Number: K050516
Product: T-SLING

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 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

28

K050516 52

CALDERA

CALDERA MEDICAL, INC.

RESPONSES TO DEFICIENCY LETTER DATED JUNE 22, 2005 FOR K050516

K050516 91 29

28632 ROADSIDE DRIVE, SUITE 260, AGOURA HILLS, CALIFORNIA 91301

818.879.6555
818.879.6556

Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Appendix A: Requested Labeling - Attached

A. Caldera T-Sling
B. Tyco IVS Tunneller
C. Herniamesh T-Sling
D. Ethicon TVT

A.

Premarket Notification for T-Sling

(b)(4)Proprietary Information-draft

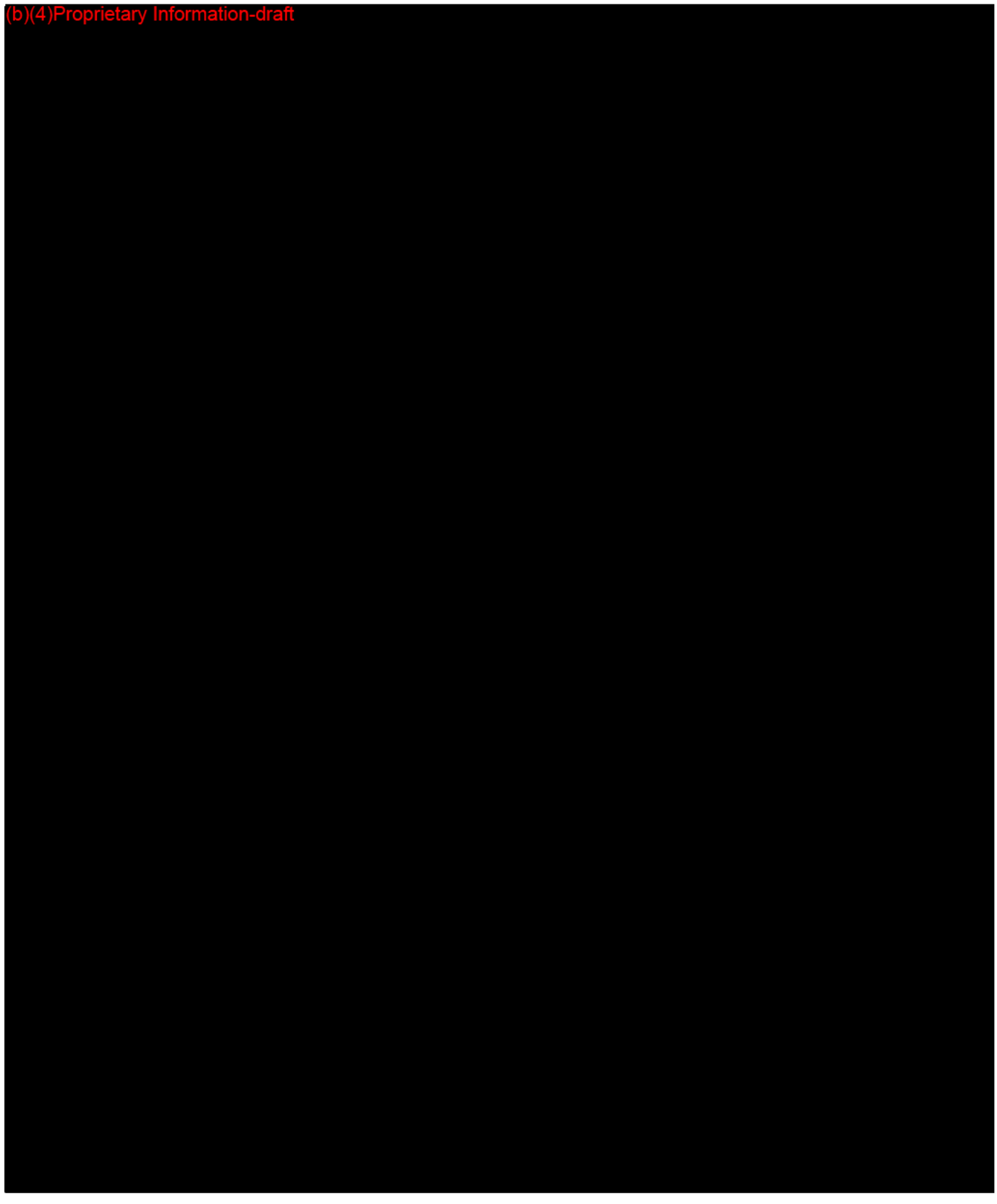
[redacted]

(b)(4)Proprietary Information-draft

[redacted] 34

(b)(4)Proprietary Information-draft

(b)(4)Proprietary Information-draft



Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Appendix B.

A. Indications for Use Form

B. Table of Similarities and Differences/Substantial Equivalence to Predicate Devices: AMENDMENT – April 7, 2005 – Rev. 1

C. T-Sling Packaging and Labeling (Inner Tyvek Pouch)

D. T-Sling Packaging and Labeling (Outer Foil Pouch)

E. T-Sling Outer Box Labeling (Front of Outer Box)

F. T-Sling Outer Box Labeling (Back of Outer Box)

A.

Premarket Notification for T-Sling

Indications for Use Form

510(k) Number: K050516

Device Name: T-Sling

Indications For Use:

The T-sling is intended to be used in females to position a mesh for treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X___ (per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

B.

Premarket Notification for T-Sling

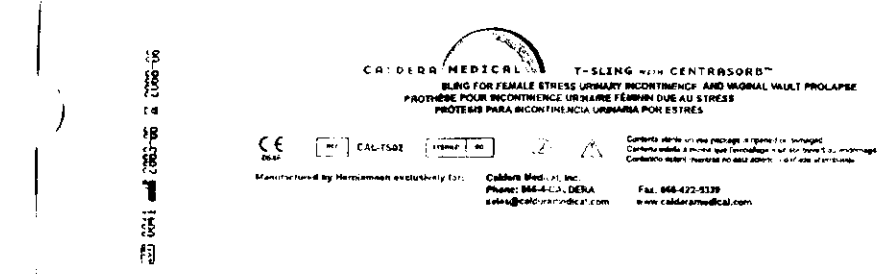
AMENDMENT – April 7, 2005 Rev. 1

Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

Feature	T-Sling	Herniamesh T-Sling	Ethicon TVT	Tyco Healthcare IVS Tunneller
510(k) No.	K050516	K020652	K012628	K010035
Classification	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh	Class II: Polymeric Surgical Mesh
Indication	(b)(4)Proprietary Information	Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency	Pubourethral sling for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency	Intended to be used in females to position a polypropylene mesh for the treatment of Genuine Stress Urinary Incontinence (SUI), mixed incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, and vaginal vault prolapse
Product Design		Pre-shaped Duel-component mesh Polypropylene and bioabsorbable polymer	Pre-shaped Polypropylene mesh	Pre-shaped Polypropylene mesh
Materials		Polypropylene & Polydioxanone (Bioabsorbable Polymer)	Polypropylene	Polypropylene
Sterilization	EtO	EtO	EtO	EtO
Packaging	(b)(4)Proprietary Information	Tyvek pouch with outer heat sealed foil pouch	PVC tray with Tyvek back	Substantially Equivalent
Size		2cm x 15cm	1.1cm x 45cm	Substantially Equivalent

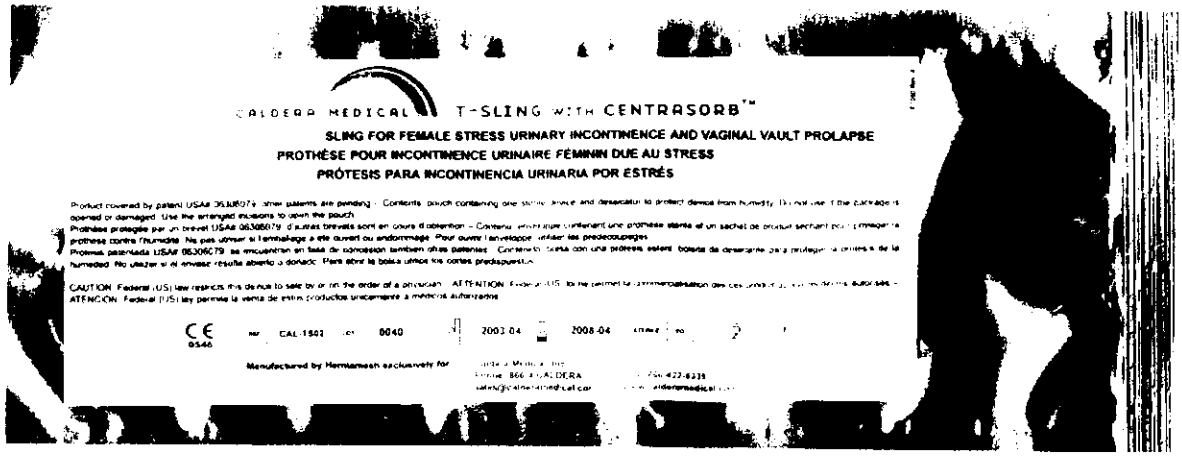
C.

T-Sling Packaging And Labeling (Inner · Tyvek Pouch)



D.

T-Sling Packaging And Labeling (Outer Foil Pouch)

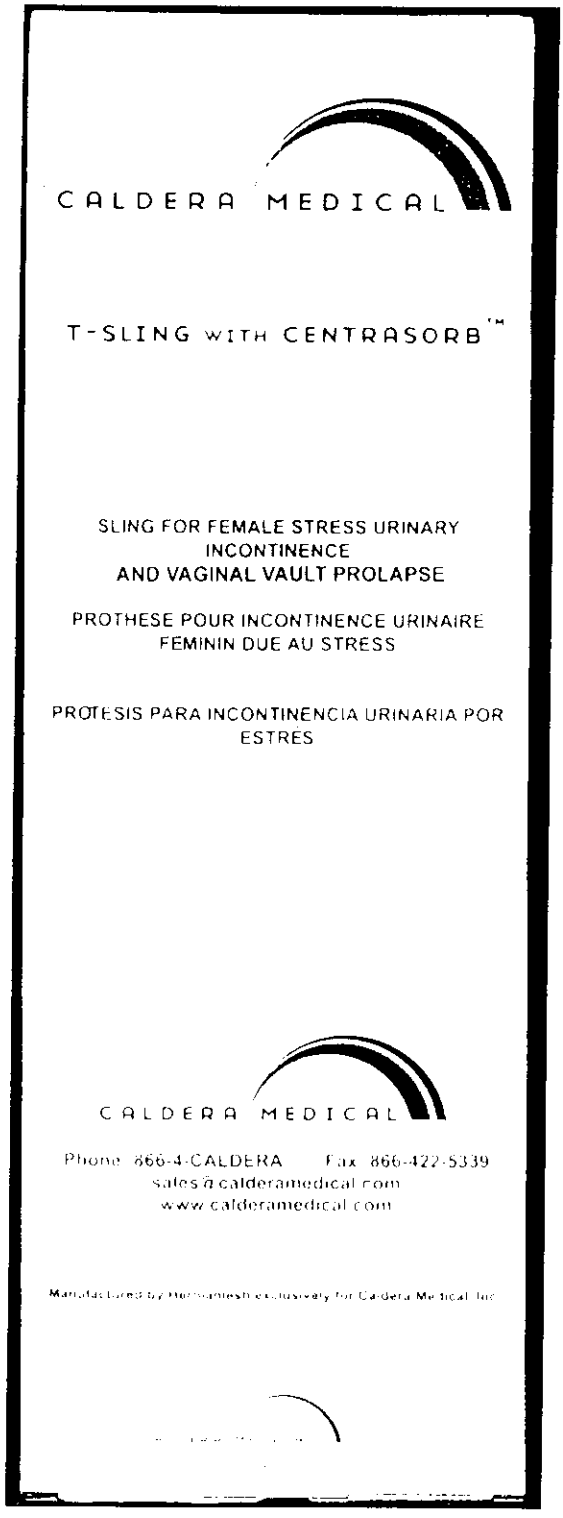


E.

Premarket Notification for T-Sling

T-Sling Outer Box Labeling (packaged 5 / box)

Front of Outer Box

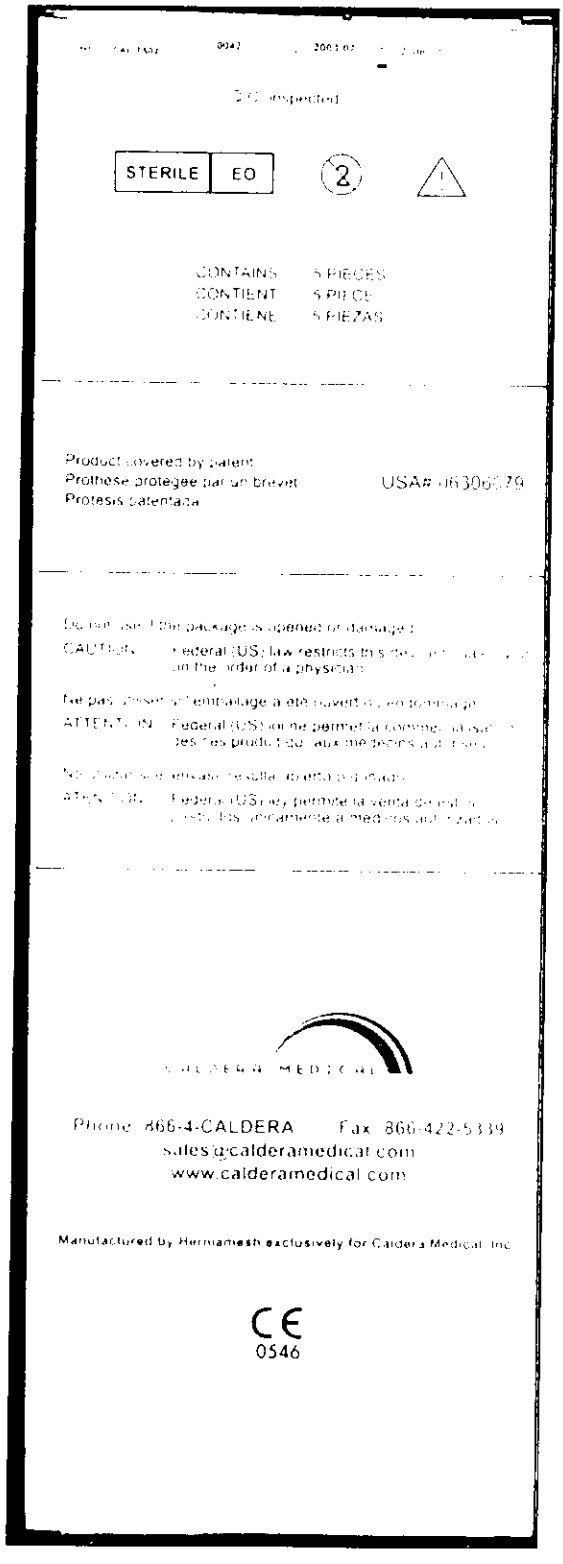


F.

Premarket Notification for T-Sling

T-Sling Outer Box Labeling (packaged 5 / box)

Back of Outer Box

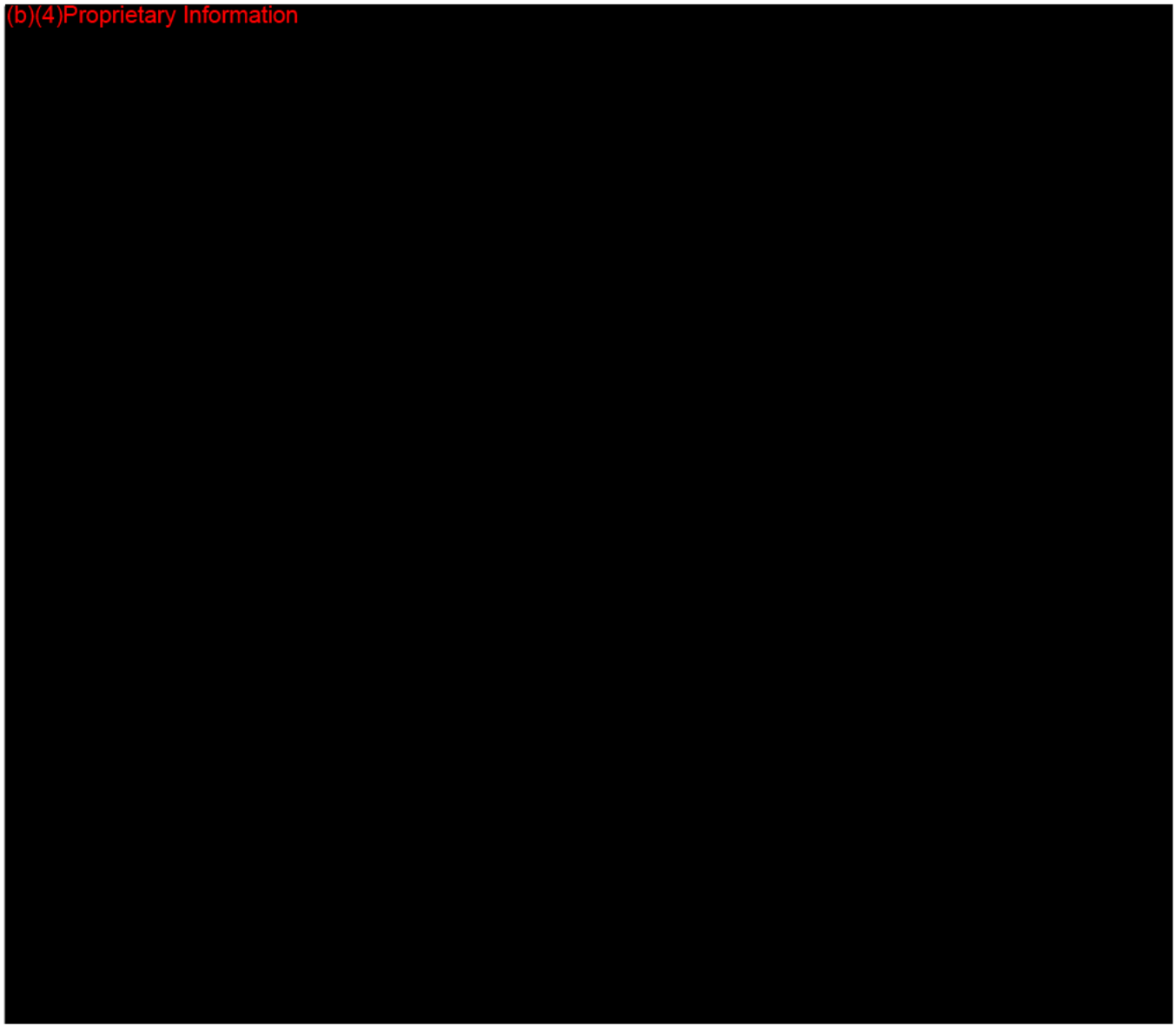


Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information



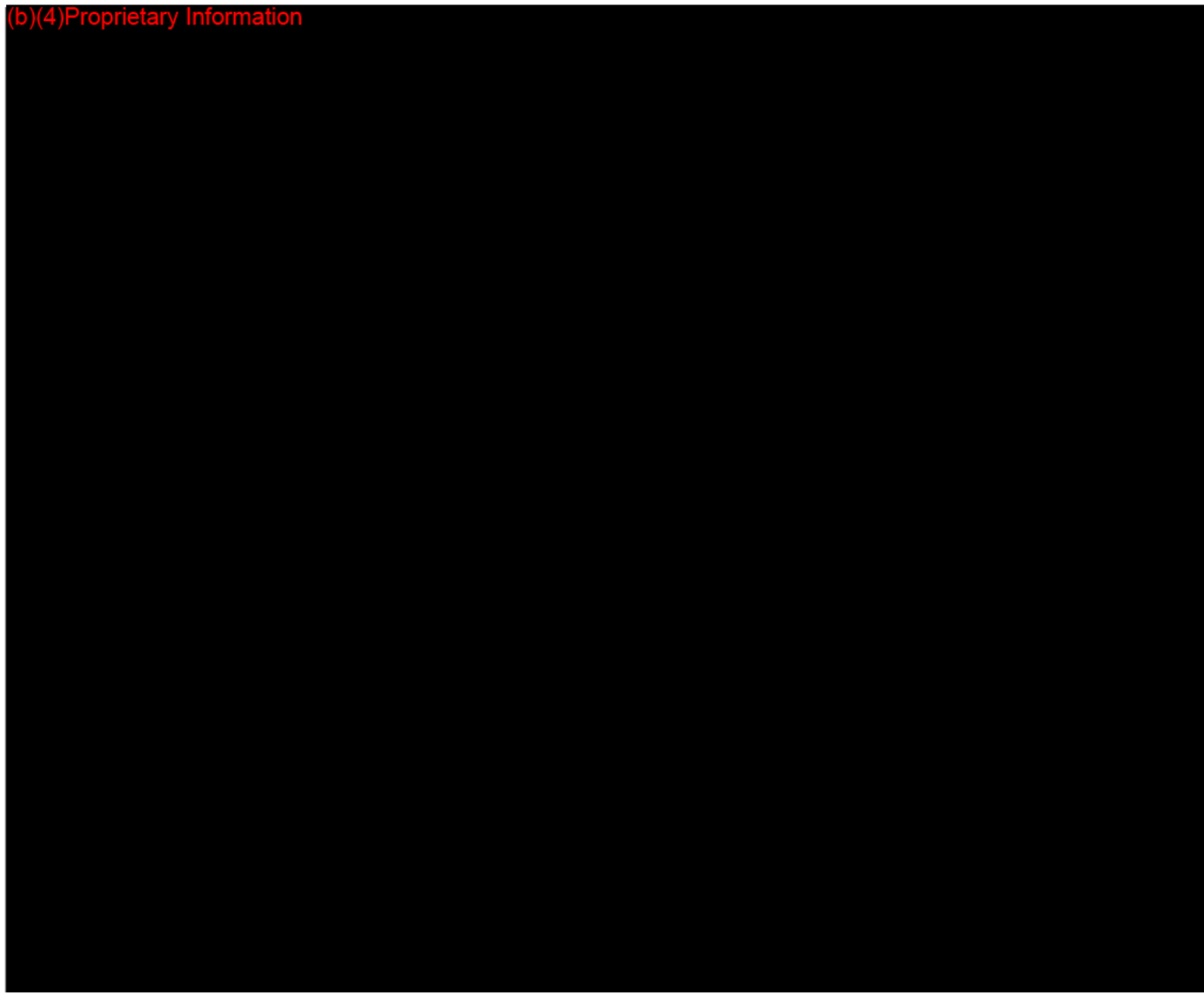
Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]



Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Statement of Indication for Use

(b)(4)Proprietary Information

[redacted]

Technological Characteristics

(b)(4)Proprietary Information

[redacted]

Scanning electron Microscopy Pictures of T-Sling

(b)(4)Proprietary Information

[redacted]

Statement of Indication for Use

(b)(4)Proprietary Information

[redacted]

Technological Characteristics

(b)(4)Proprietary Information

[redacted]

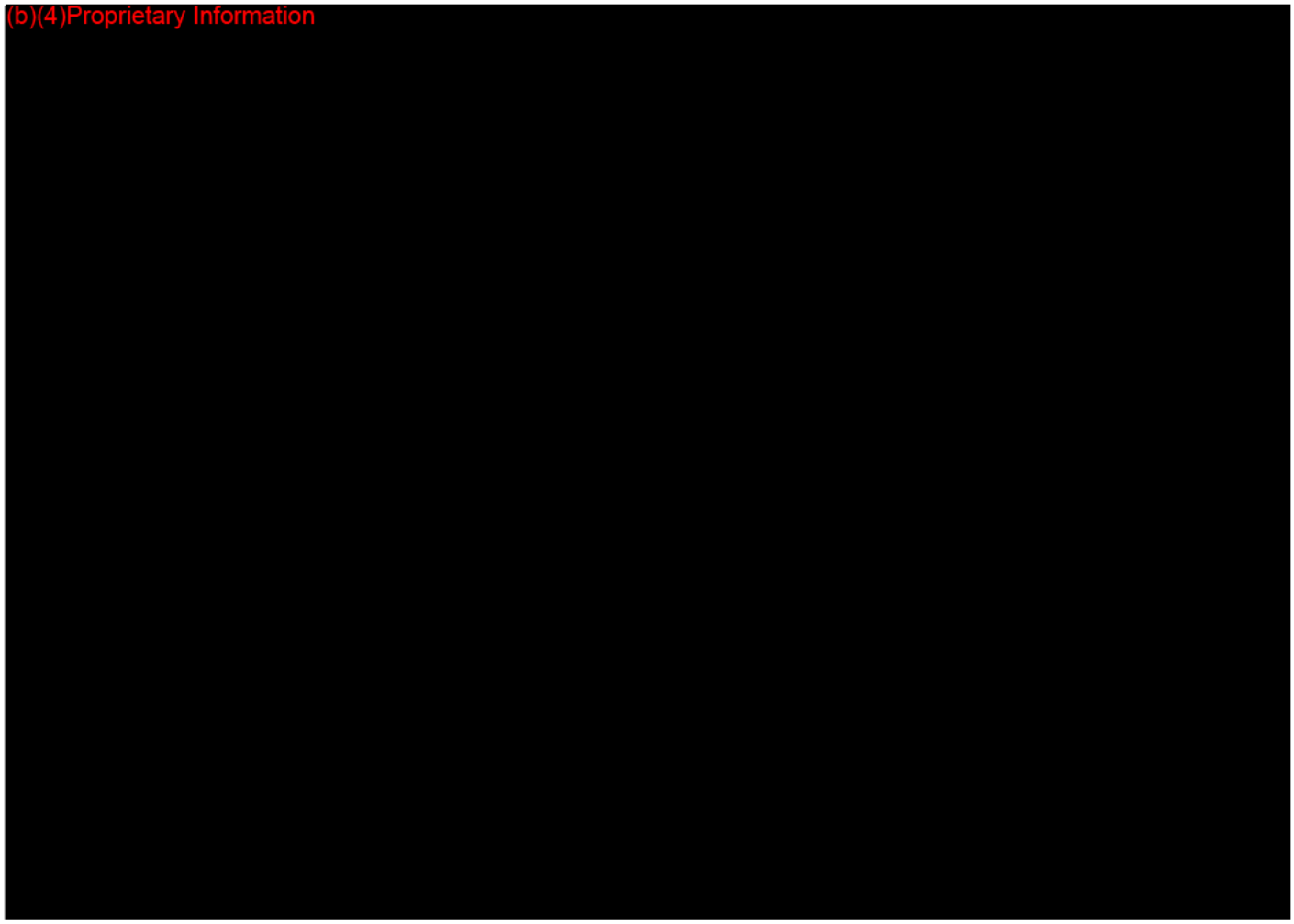
Scanning electron Microscopy Pictures of T-Sling

(b)(4)Proprietary Information

[redacted]

Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

(b)(4)Proprietary Information



Appendix C.

Certification Letter from Herniamesh

(b)(4)Proprietary Information

Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Caldera Medical, Inc.

November 28, 2005

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Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Biocompatibility Flow Chart for the Selection of Toxicity Tests for 510(k)s

(b)(4)Proprietary Information

Caldera Medical, Inc.

November 28, 2005

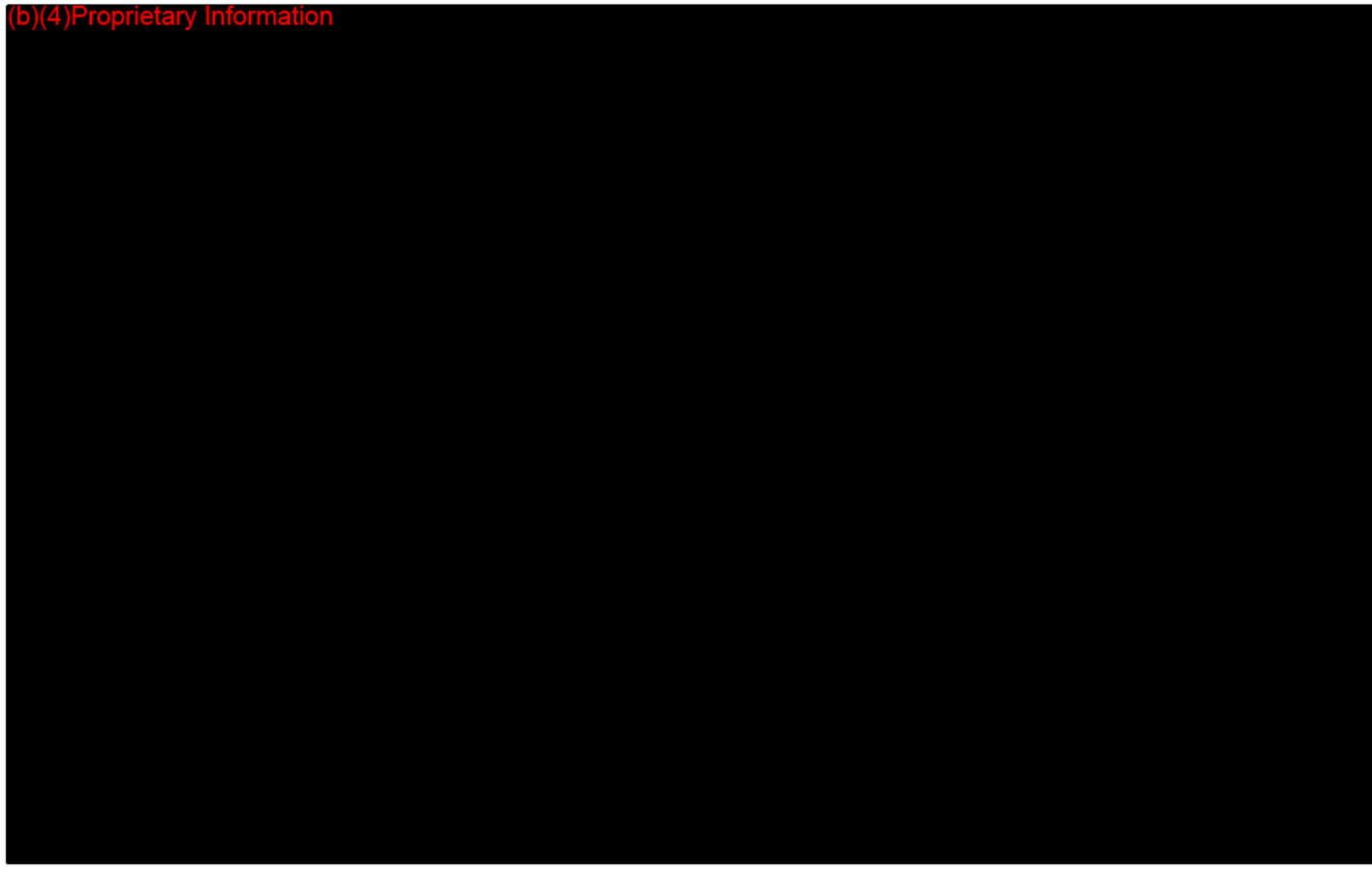
Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

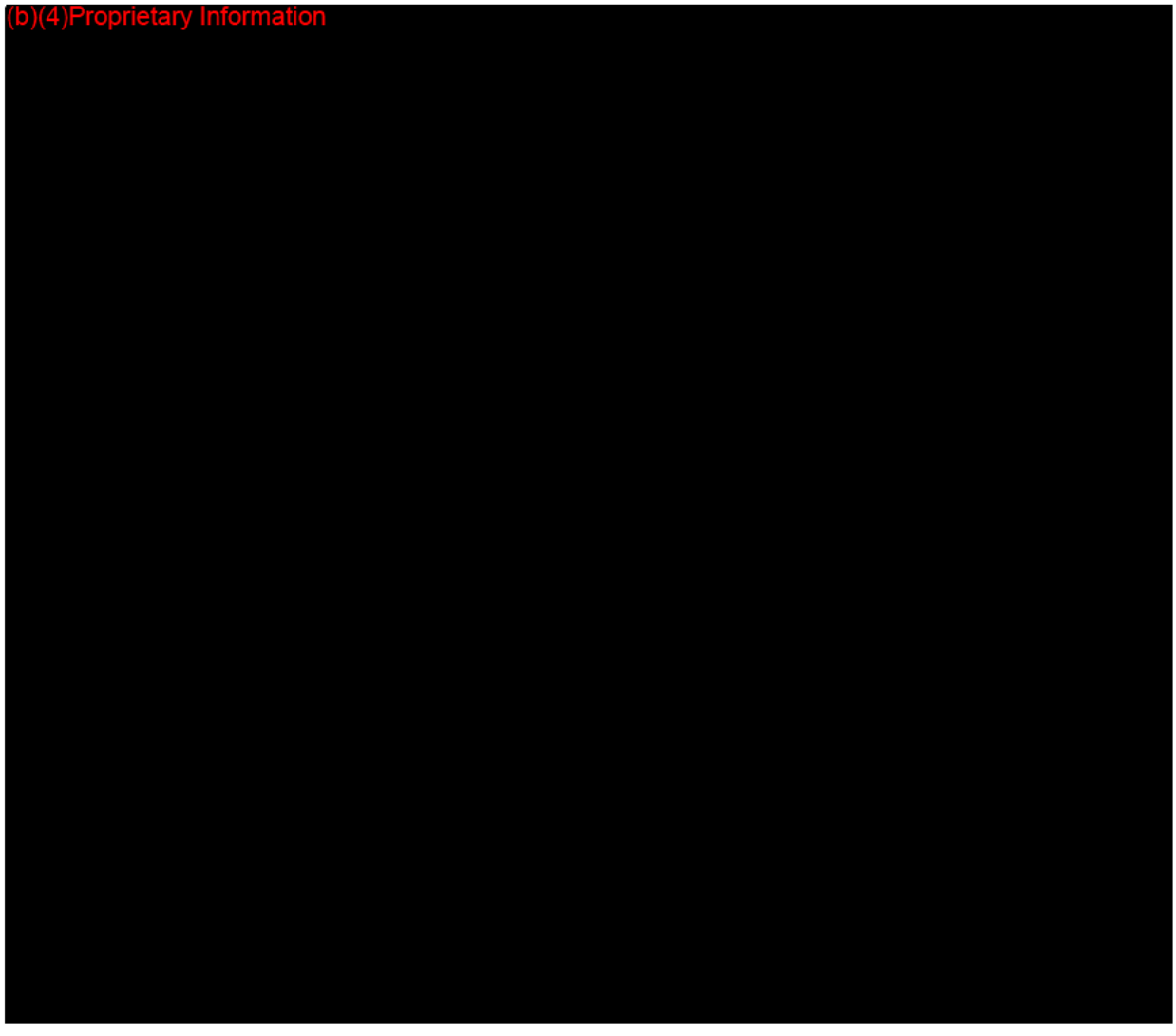
Table of Similarities and Differences / Substantial Equivalence to Predicate Devices

(b)(4)Proprietary Information



Safety, Efficacy and Performance Results

(b)(4)Proprietary Information



November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

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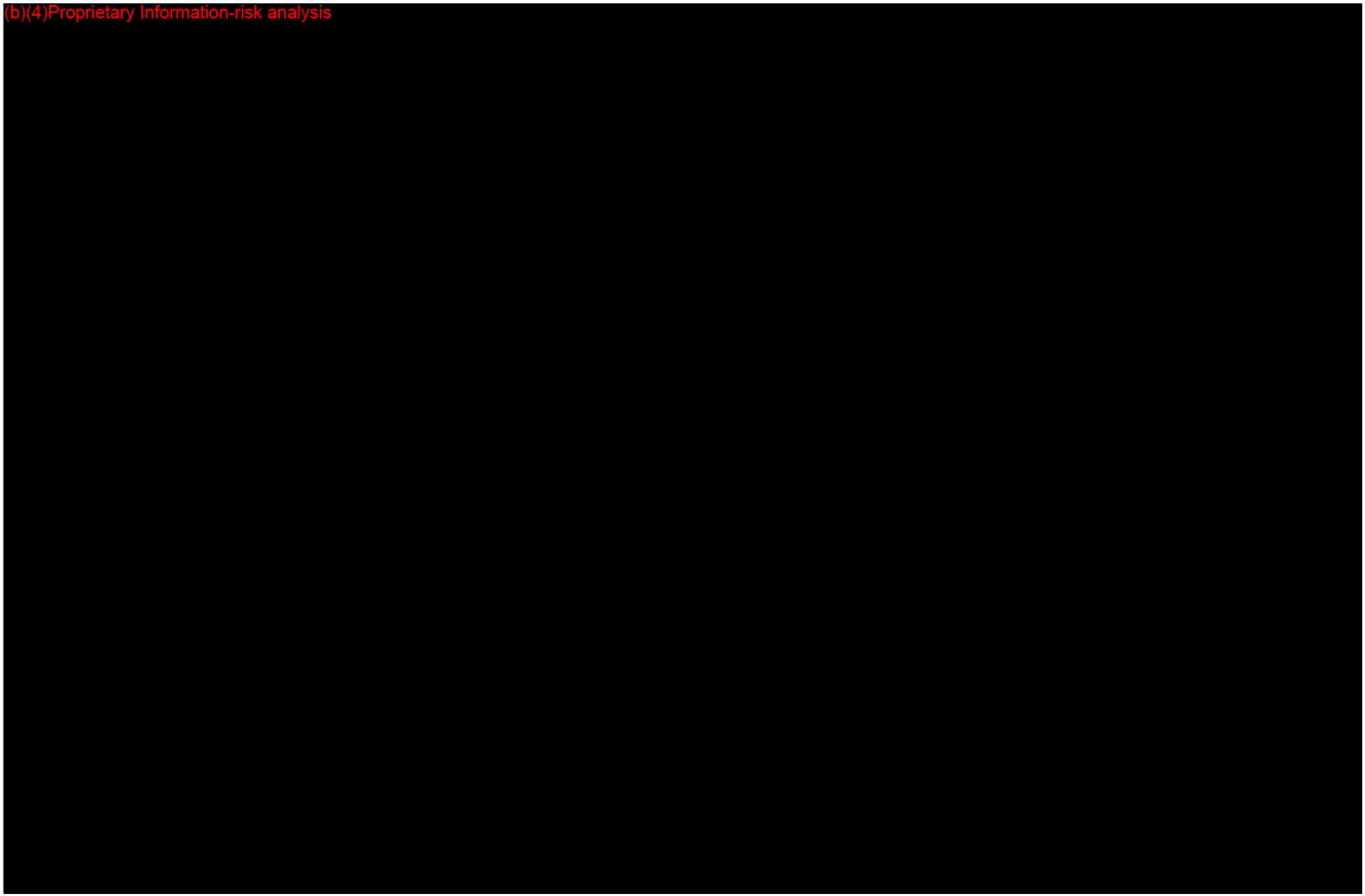
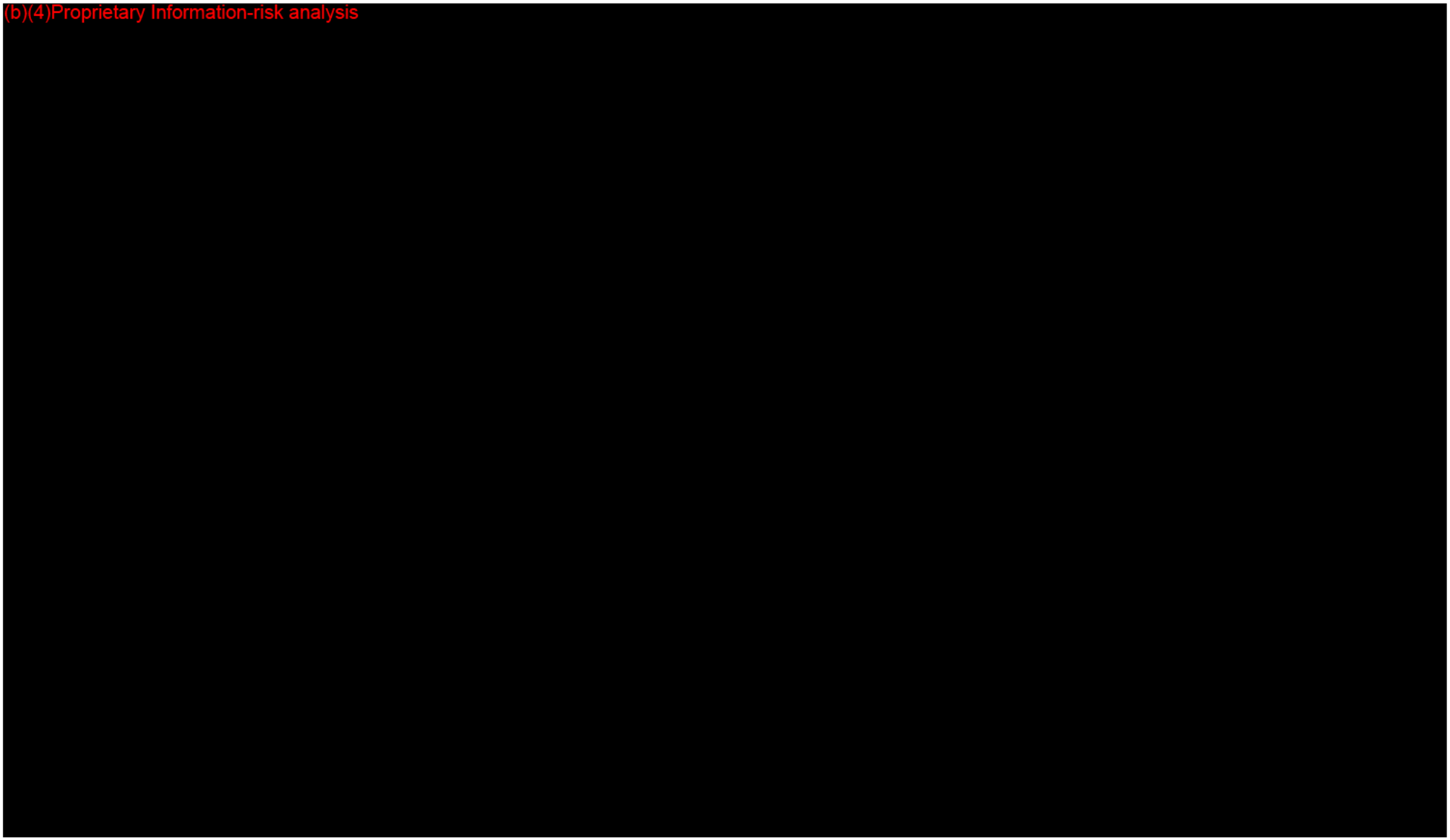
RISK MANAGEMENT SUMMARY REPORT



(b)(4)Proprietary Information-risk analysis



RISK MANAGEMENT SUMMARY REPORT

(b)(4)Proprietary Information-risk analysis

Caldera Medical, Inc.

November 28, 2005

Re: K050516/S001
Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

November 28, 2005

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Trade Name: T-Sling
Deficiency Responses to Letter Dated June 22, 2005

(b)(4)Proprietary Information

[redacted]

Caldera Medical, Inc.

November 28, 2005

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(b)(4)Proprietary Information

[redacted]

65

Caldera Medical, Inc.

November 28, 2005

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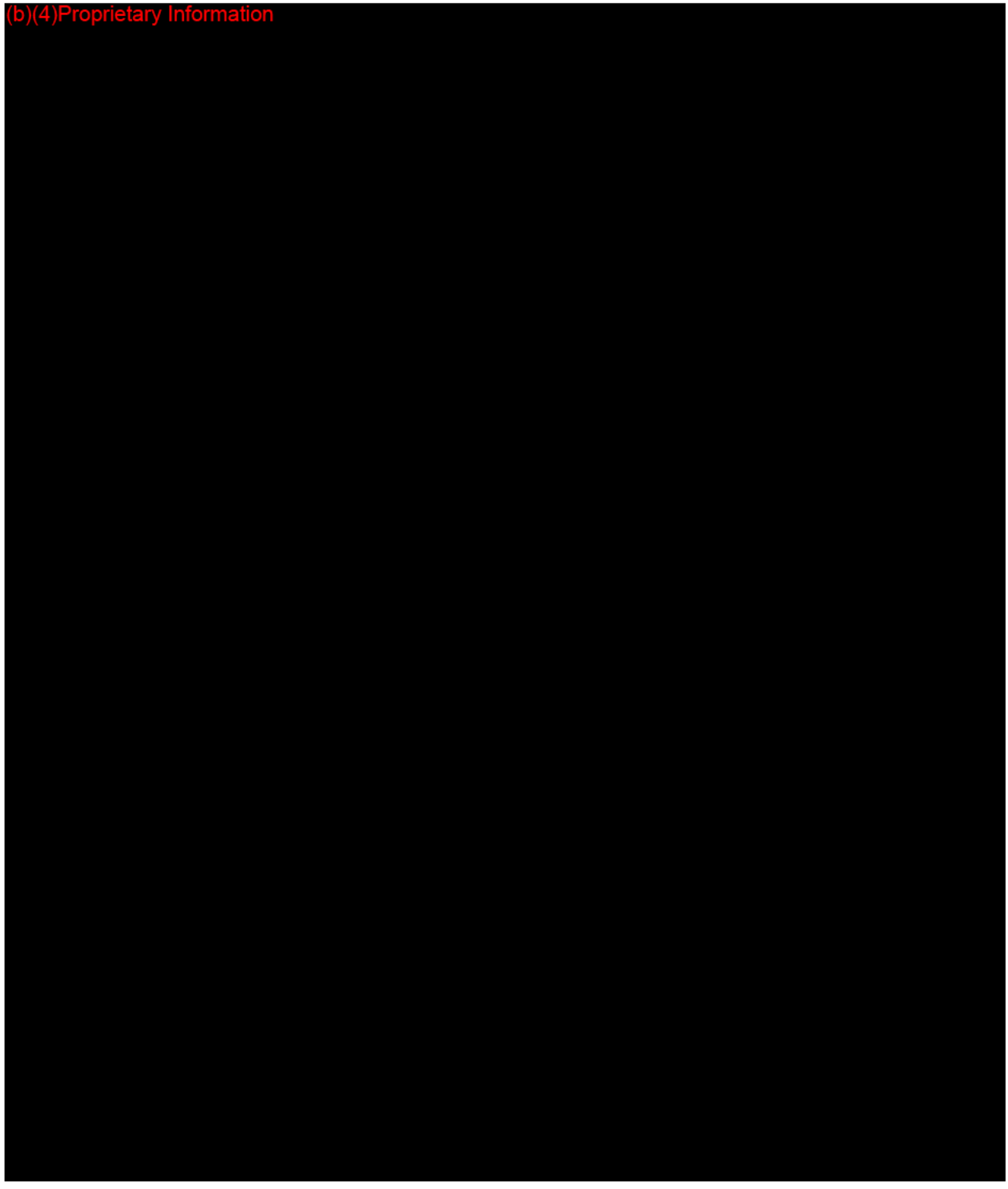

Caldera Medical, Inc.

November 28, 2005

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(b)(4)Proprietary Information

[redacted]

67

Caldera Medical, Inc.

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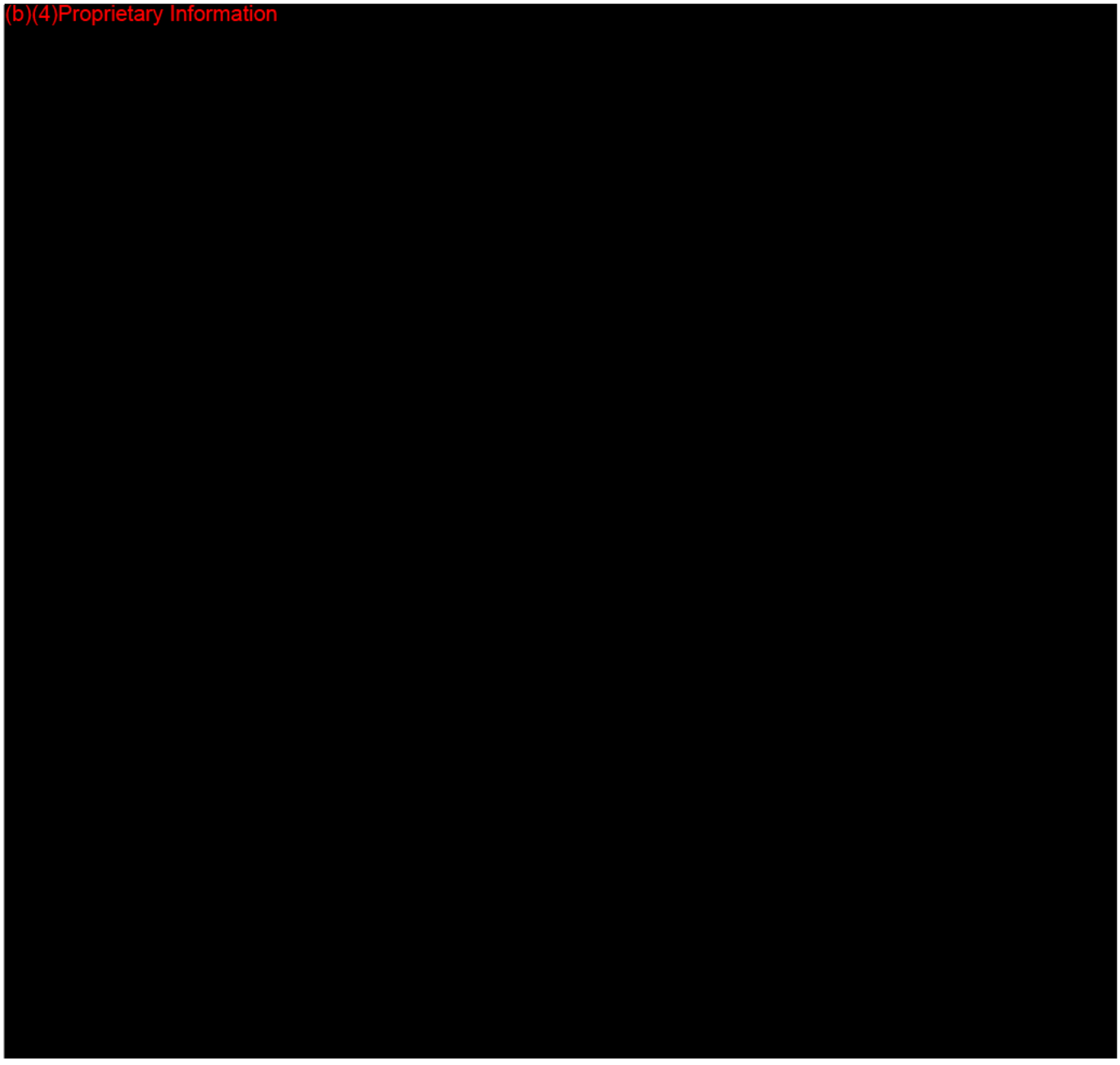

(b)(4)Proprietary Information-Testing

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