



USER: GRAY, ILKA K (ixg)

FOLDER: K090094 - 474 pages (FOI:01007306)

COMPANY: ZELTIQ AESTHETICS (ZELTAEST)

PRODUCT: POWERED LASER SURGICAL INSTRUMENT
(GEX)

SUMMARY: Product: ZELTIQ SYSTEM

DATE REQUESTED: Wed Nov 10 24:00:00 2010

DATE PRINTED: Thu Jan 20 09:16:53 2011

Note: Releasable Version

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SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

MAY 20 2009

TRADE NAME: Zeltiq System

COMMON NAME: Skin Refrigerant

CLASSIFICATION NAME: Laser instrument, surgical, powered

DEVICE CLASSIFICATION: Class II, 21 CFR §878.4810

PRODUCT CODE 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA - massager, therapeutic, electric

PREDICATE DEVICE: The Zeltiq System is substantially equivalent to the Zeltiq CLN1 Dermal Cooling Device (K080118).

SUBSTANTIALLY EQUIVALENT TO:

The Zeltiq System has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device (K080118).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage and an optional paging device.

INDICATION FOR USE:

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator. The system includes an optional paging device.

PERFORMANCE DATA:

Testing confirms that the Zeltiq System can be used in an equivalent manner to the predicate device.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq System are the same as for the predicate device cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq System is functionally equivalent to the predicate device.



MAY 20 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Zeltiq System
% Mr. Donald V. Johnson
VP, Operations, Regulatory and
Quality Affairs
4698 Willow Road
Pleasanton, California 94588

Re: K090094

Trade/Device Name: Zeltiq System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology

Regulatory Class: II

Product Code: GEX, ILO, ISA

Dated: May 7, 2009

Received: May 11, 2009

Dear Mr. Johnson:

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 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.

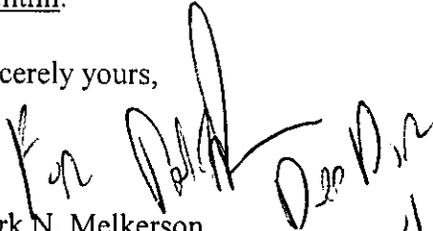
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

Page 2 - Mr. Donald V. Johnson

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

5/17/09

Enclosure

K090094

SECTION 5.

INDICATIONS FOR USE STATEMENT

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Zeltiq System

Indications for Use:

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Oyster
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page ___ of ___

510(k) Number K090094



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 20 2009

Food and Drug Administration,
9200 Corporate Boulevard
Rockville MD 20850

Zeltiq System
% Mr. Donald V. Johnson
VP, Operations, Regulatory and
Quality Affairs
4698 Willow Road
Pleasanton, California 94588

Re: K090094

Trade/Device Name: Zeltiq System
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Regulation Name: Laser surgical instrument for use in general and plastic surgery
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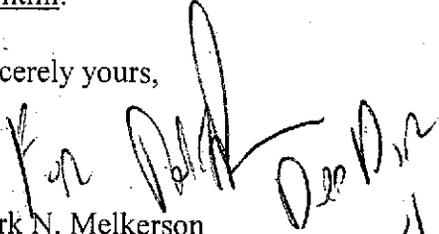
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Page 2 - Mr. Donald V. Johnson

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Sincerely yours,


Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

5/17/09

Enclosure

K090094

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Prescription Use x
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AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Oyden, M.D.
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Page ___ of ___

510(k) Number K090094

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March 09, 2009

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON

510k Number: K090094

Product: ZELTIQ SYSTEM

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 additional information (AI), 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 (21 CFR 807.87(l)). 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". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. 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.

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 questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



February 09, 2009

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON

510k Number: K090094

Product: ZELTIQ SYSTEM

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.

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If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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January 16, 2009

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON

510k Number: K090094

Received: 1/15/2009

Product: ZELTIQ SYSTEM

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

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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



January 15, 2009

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON510k Number: K090094
Received: 1/14/2009
User Fee ID Number: 6040736
Product: ZELTIQ SYSTEM

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all 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 Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full; therefore, the file has been placed on hold. When your user fee payment has been received, review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular MailFood and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733By 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 (240)276-4025 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 www.fda.gov/oc/mdufma.

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

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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 a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (240)276-4027. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane M. Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

K090094

January 13, 2009

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

FDA CDRH DMC

JAN 14 2009

RE: Premarket Notification for the Zeltiq System

Received

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

OFFICIAL Donald Johnson
CORRESPONDENT Vice President, Operations, Regulatory, & Quality Affairs
Phone (b)(4)
Fax (b)(4)
e-mail: (b)(4)

DEVICE
CLASSIFICATION Class II, 21 CFR §878.4810
PRODUCT CODES 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA – massager, therapeutic, electric

Dear CDRH Staff:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of Zeltiq Aesthetics, Inc. to market and distribute the Zeltiq System, an upgrade to the cleared Zeltiq CLN1 Dermal Cooling Device (K080118, cleared May 2, 2008). The upgraded Zeltiq System includes:

- Improvements to the control unit industrial design and interface with applicators;
- Re-design of the vacuum applicator and sleeve to incorporate the cup into the consumable sleeve;
- (b)(4) (b)(4)
- (b)(4) (b)(4)
- Software improvements were made to improve the graphical user interface, the (b)(4) (b)(4)

The upgrade has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device (K080118).

This submission has been formatted per the recommendations made by the Agency in the Guidance: "How To Prepare A Special 510(k)", issued on November 13, 2007. The required Declaration of Conformity to Design Controls is provided as Attachment 13-1 of this submission.

Zeltiq regards information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21 CFR 807.95 and other applicable regulations and statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness is included in this notification. A CD with an electronic version of this submission is enclosed for the reviewers' convenience.

We trust that this submission will be satisfactory for review. If there are any questions, or if additional information is required, please contact me at (b)(4) or by email at (b)(4) (b)(4)

Sincerely,



Donald Johnson

Vice President, Operations, Regulatory, and Quality Affairs
Zeltiq Aesthetics, Inc.

510(k) PREMARKET NOTIFICATION FOR THE
ZELTIQ SYSTEM

APPLICANT

Zeltiq Aesthetics, Inc
4698 Willow Road
Pleasanton, CA 94588

OFFICIAL CORRESPONDENT

Donald Johnson
Vice President, Operations & Quality Affairs
Phon (b)(4)
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**510(k) PREMARKET NOTIFICATION FOR THE
ZELTIQ CLN1 DERMAL COOLING DEVICE
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1. MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b) (4) Write the Payment Identification number on		
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) ZELTIQ AESTHETICS, INC. 4698 Willow Road, Suite 100 Pleasanton CA 94588 US ER IDENTIFICATION NUMBER (EIN) (b) (4)	2. CONTACT NAME Donald Johnson 2.1 E-MAIL ADDRESS (b) (4) 2.2 NUMBER (include Area code) (b) (4) 2.3 FACSIMILE (FAX) NUMBER (Include Area code) (b) (4)		
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: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice </td> <td style="width: 50%; vertical-align: top;"> 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) </td> </tr> </table>		<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially </td> </tr> </table>		<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
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7. 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)). <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
8. PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b) (4)			

2. CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 01/13/2009	User Fee Payment ID Number MD6040736-956733	FDA Submission Document Number (if known)
----------------------------------	------------------------------------------------	-------------------------------------------

SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Zeltiq Aesthetics, Inc.		Establishment Registration Number (if known) 3007215625	
Division Name (if applicable) NA		Phone Number (including area code) (b)(4)	
Street Address 4698 Willow Road		FAX Number (including area code) (b)(4)	
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Donald V. Johnson			
Contact Title Vice President, Operations, Regulatory and Quality Affairs		Contact E-mail Address (b)(4)	

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (<i>specify below</i>)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (*specify*):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (<i>specify</i>):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Premarket notification covering modifications to the existing CLN1 Dermal Cooling device cleared under K080118.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1 79 GEX	2 89 IOL	3 89 ISA	4	
5	6	7	8	

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	K080118	1 CLN1 Dermal Cooling Device	1 Zeltiq Aesthetics, Inc.
2		2	2
3		3	3
4		4	4
5		5	5
6		6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
Zeltiq System

	Trade or Proprietary or Model Name for This Device	Model Number
1		1
2		2
3		3
4		4
5		5

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

1 K060407	2 K063715	3 K072152	4 K080118	5 K080521	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code 79 GEX	C.F.R. Section (if applicable) 21 CFR 878.4810	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General and Plastic Surgery		

Indications (from labeling)
 The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number <i>(if known)</i>	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Zeltiq Aesthetics, Inc.		Establishment Registration Number 3007215625	
Division Name <i>(if applicable)</i> NA		Phone Number <i>(including area code)</i> (b) (4)	
Street Address 4698 Willow Road		FAX Number <i>(including area code)</i> (b) (4)	
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Donald V. Johnson	Contact Title Vice President, Operations, Quality and Regulatory Affairs	Contact E-mail Address (b) (4)	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> ()	
Street Address		FAX Number <i>(including area code)</i> ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name <i>(if applicable)</i>		Phone Number <i>(including area code)</i> ()	
Street Address		FAX Number <i>(including area code)</i> ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ISO 13485	ISO	Medical devices -- Quality management systems -- Requirements for regulatory purposes	2 nd edition	07/15/2003
2	ISO 14971	ISO	Medical devices -- Application of risk management to medical devices	2 nd edition	03/01/2007
3	ISO 10993-1	ISO	Biological evaluation of medical devices --Part 1: Evaluation and testing	3 rd edition	08/01/2003
4	ISO 10993-5	ISO	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	2 nd edition	05/15/1999
5	ISO 10993-10	ISO	Biological evaluation of medical devices -- Part 10: Tests for irritation and delayed-type hypersensitivity	2 nd edition	09/01/2002
6	IEC 60601 -1	IEC	Medical electrical equipment Part 1: General requirements for safety	2 nd edition + A1:1991 + A2:1995	03/01/1995
7	IEC 60601-1-4	IEC	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable electrical medical system	1 st edition+ A1: 1999	10/29/1999

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	IEC 60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral Standard - Electromagnetic Compatibility - Requirements and Tests	Edition 2.1 +A1:2004 2001	11/01/2004
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

**3. CERTIFICATION OF COMPLIANCE WITH CLINICALTRIALS.GOV DATA BANK
(FDA-3674)**



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

(b) (4)

(b)(4)

4. COVER LETTER



January 13, 2009

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

RE: Premarket Notification for the Zeltiq System

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

OFFICIAL Donald Johnson
CORRESPONDENT Vice President, Regulatory, & Quality Affairs
Pho (b)(4)
Fax (b)(4)
e-m (b)(4)

DEVICE
CLASSIFICATION Class II, 21 CFR §878.4810
PRODUCT CODES 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA – massager, therapeutic, electric

Dear CDRH Staff:

Pursuant to the provision of Section 510(k) of the Federal Food, Drug and Cosmetic Act and the Safe Medical Devices Act of 1990, notification is made of the intention of Zeltiq Aesthetics, Inc. to market and distribute the Zeltiq System, an upgrade to the cleared Zeltiq CLN1 Dermal Cooling Device ([K080118](#), cleared May 2, 2008). The upgraded Zeltiq System includes:

- Improvements to the control unit industrial design and interface with applicators;
- Re-design of the vacuum applicator and sleeve to incorporate the cup into the

- (b)(4) (b)(4)

- (b)(4) (b)(4)

- (b)(4) e (b)(4)

The upgrade has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device (K080118).

This submission has been formatted per the recommendations made by the Agency in the Guidance: "How To Prepare A Special 510(k)", issued on November 13, 2007. The required Declaration of Conformity to Design Controls is provided as Attachment 13-1 of this submission.

Zeltiq regards information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21 CFR 807.95 and other applicable regulations and statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness is included in this notification. A CD with an electronic version of this submission is enclosed for the reviewers' convenience.

We trust that this submission will be satisfactory for review questions, or if additional information is required, please contact me at (b)(4) or by email at (b)(4) (b)(4).

Sincerely,

Donald Johnson
Vice President, Operations, Regulatory, and Quality Affairs
Zeltiq Aesthetics, Inc.

SECTION 5.

INDICATIONS FOR USE STATEMENT

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Zeltiq System

Indications for Use:

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post-traumatic and / or post-surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page __ of __

SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

TRADE NAME: Zeltiq System

COMMON NAME: Skin Refrigerant

CLASSIFICATION NAME: Laser instrument, surgical, powered

DEVICE CLASSIFICATION: Class II, 21 CFR §878.4810

PRODUCT CODE 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA - massager, therapeutic, electric

PREDICATE DEVICE: The Zeltiq System is substantially equivalent to the Zeltiq CLN1 Dermal Cooling Device ([K080118](#)).

SUBSTANTIALLY EQUIVALENT TO:

The Zeltiq System has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device ([K080118](#)).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage and an optional paging device.

INDICATION FOR USE:

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post-traumatic and/or post-surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator. The system includes an optional paging device.

PERFORMANCE DATA:

Testing confirms that the Zeltiq System can be used in an equivalent manner to the predicate device.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq System are the same as for the predicate device cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq System is functionally equivalent to the predicate device.

SECTION 7.

TRUTHFUL & ACCURATE STATEMENT

7. TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(j) I certify that in my capacity as Vice President, Operations, Quality, and Regulatory Affairs of Zeltiq Aesthetics, Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Donald Johnson

Date

Vice President, Operations, Quality, & Regulatory Affairs

SECTION 8.

CLASS III SUMMARY AND CERTIFICATION

8. CLASS III SUMMARY AND CERTIFICATION

The Zeltiq System is a Class II medical device regulated under 21 CFR §878.4810. Thus, the Class III Summary and Certification requirement as described in 21 CFR §807.87(j) and §807.94 does not apply to this device and submission.

SECTION 9.

FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

9. FINANCIAL CERTIFICATION OR DISCLOSURE STATEMENT

The requirement for financial certification or disclosure requirement as described in 21 CFR §807.87(i) does not apply to this submission.

10. EXECUTIVE SUMMARY

There is no change to the intended use or mechanism of action in this premarket notification for the Zeltiq System. This submission for the Zeltiq System includes the following design enhancements:

Component	Enhancements
Zeltiq Breeze Control Unit (incl. software)	<ul style="list-style-type: none"> • Improved industrial design of unit • Redesign umbilical support arm for improved ergonomics • Separable upper and lower modules • Increased size of touch screen display • Integrated (all-in-one) interface between control unit • (b) (4) • (b)(4) • applicators) • (b) (4) (b)(4) • user interface – Improved control algorithm – Patient call functionality – Improved error handling
Zeltiq Breeze Applicator (belt and vacuum)	<ul style="list-style-type: none"> • Re-designed vacuum applicator; flexible cup has now been designed into the sleeve • Improved electrical interconnect between sleeve and applicator for improved reliability • (b) (4) (b)(4) • control unit
Zeltiq AcuCool Sleeve (belt and vacuum)	<ul style="list-style-type: none"> • (b) (4) (b)(4) • g • (b) (4) (b)(4) • (b) (4) (b)(4)
Zeltiq Gelpad Zeltiq Gel	<ul style="list-style-type: none"> • (b) (4) (b)(4)

10.1. INTENDED USE

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post-traumatic and / or post-surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

10.2. PREDICATE DEVICE

The Zeltiq System has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device ([K080118](#)).

Table 1. Substantial Equivalence Matrix for the Zeltiq System

Element	Zeltiq System (subject of this submission)	Zeltiq CLN 1 Dermal Cooling Device K080118	
Indications for Use	<ul style="list-style-type: none"> ... used to minimize pain and thermal injury during laser and dermatological treatments... 	<ul style="list-style-type: none"> • Same 	
	<ul style="list-style-type: none"> Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort; 	<ul style="list-style-type: none"> • Same 	
	For Hot/Cold Therapy...		
	<ul style="list-style-type: none"> localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain; 	<ul style="list-style-type: none"> • Same 	
	<ul style="list-style-type: none"> for temporary relief of minor aches and pains and muscle spasms; 	<ul style="list-style-type: none"> • Same 	
	Massage Therapy...		
Principle of Operation			
Skin cooling / heating mechanism	Flat or cupped applicator, applied topically	<ul style="list-style-type: none"> • Same 	
Applicator interface surface area	(b) (4) (d)	<ul style="list-style-type: none"> • Same 	
Temperature control mechanism	Thermoelectric	<ul style="list-style-type: none"> • Same 	
Treatment temperatures	(b) (4) (d)	<ul style="list-style-type: none"> • Same 	
Maximum recommended application time	(b) (4) (d) depending on application conditions	<ul style="list-style-type: none"> • Same 	
Vacuum function	Create skin fold	<ul style="list-style-type: none"> • Same 	
Massage (e.g., mechanical manipulation)	Yes – electrically powered (vibration or pulsatile vacuum)	<ul style="list-style-type: none"> • Same 	
Massage with simultaneous heating	Yes, optional	<ul style="list-style-type: none"> • Same 	

SECTION 10.

EXECUTIVE SUMMARY

Element	Zeltiq System (subject of this submission)	Zeltiq CLN 1 Dermal Cooling Device K080118
Massage/cooling	Yes, possible contact cooling at skin. Precaution in DFU: "The effects of simultaneous use of massage and cold with the Zeltiq CLN1 Dermal Cooling Device have not been established, and such simultaneous use should be avoided."	• Same
Design Features		
General Design	Unit attached to a hand-held patient interface; optional strap available for hands-free tion	• Same
Temperature accuracy	(b) (4)	• Same
Temperature display	LCD Touchscreen	• Same
Power Source	AC	• Same
Microprocessor controlled	Yes	• Same
Safety Shut-off	Yes – auto shut off	• Same
Console with electrically powered vacuum pump	Yes	• Same
Pulsatile vacuum	Yes	• Same
Suction power	(b) (4)	• Same
Frequency		• Same
Cycle rate	50%	• Same
Power Source	120 VAC/ 60 Hz	• Same
Sterility	Non sterile	• Same
Other Features		
Reusable	Yes	• Same

10.3. PERFORMANCE STANDARDS

No performance standards have been established by the Agency to date that apply to this device.

10.4. BENCH & ANIMAL TESTING

Bench testing (verification and validation) and software validation demonstrate that the system can (b)(4) (b)(4)

(b)(4) The testing design specification parameters. Testing is summarized in Section 12, Summary of Design Control Activities.

11. GENERAL DEVICE DESCRIPTION

Like the earlier version of the device, the Zeltiq System is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. Similar to the earlier versions, the Zeltiq System consists of the following components:

- Zeltiq Breeze Control Unit: Portable control unit with an integrated computer and touch screen for input/display and control;
- Zeltiq Breeze Applicator (belt and vacuum styles are available): Detachable component that cools or heats the skin and optionally provides massage;
- Zeltiq AcuCool Sleeve (belt and vacuum styles are available): Disposable sleeve to be placed between the gelpad and the applicator and (b)(4) (b)(4)
- (b)(4) (b)(4) able gel-soaked pad that is the primary patient contact surface used to facilitate thermal exchange and mitigate minor thermal variances; and
- Zeltiq Gel: Proprietary coupling gel that facilitates thermal exchange and mitigates minor thermal variances.

The arrangement of Zeltiq device components is illustrated below in Figure 1 showing the thermal path between the patient skin and the Zeltiq applicator used to cool or heat underlying tissue during a treatment.

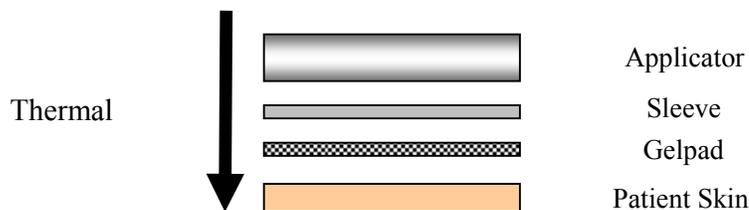


Figure 1: Illustration of Thermal Path

The following table outlines the design enhancements included as part of the Zeltiq System that represent changes from the Zeltiq CLN1 Dermal Cooling Device.

Table 2: Summary of Design Modifications	
Component	Enhancements
Zeltiq Breeze Control Unit (incl. software)	<ul style="list-style-type: none"> • Improved industrial design of unit • Redesign umbilical support arm for improved ergonomics • Separable upper and lower modules • Increased size of touch screen display • Integrated (all-in-one) interface between control unit • (b)(4) • (b)(4)

Component	Enhancements
	<ul style="list-style-type: none"> Adjustable voltage power supply (to support future (b)(4) (b)(4) ser interface <ul style="list-style-type: none"> Improved control algorithm Patient call functionality Improved error handling
Zeltiq Breeze Applicator (belt and vacuum)	<ul style="list-style-type: none"> Re-designed vacuum applicator; flexible cup has now been designed into the sleeve for ease of use Improved electrical interconnect between sleeve and applicator for improved reliability (b)(4) (b)(4) ontrol unit and applicator
Zeltiq AcuCool Sleeve (belt and vacuum)	<ul style="list-style-type: none"> (b)(4) (b)(4) in vacuum sleeve, including (b)(4) (b)(4) (b)(4) (b)(4)
Zeltiq Gelpad	<ul style="list-style-type: none"> (b)(4)
Zeltiq Gel	<ul style="list-style-type: none"> (b)(4) (b)(4)

11.1. CONTROL UNIT

The control unit (Figure 2) is a portable device that can be easily positioned prior to treatment. The control unit consists of a base and an upper module. Together, these modules include the user interface, liquid chiller, vacuum pump, control electronics and a medical grade isolation transformer to isolate all electrical components. The control unit also includes a storage area for the sleeves and gel/gelpads.

As seen in Figure 2, the overall industrial design of the control unit has been improved in appearance, ergonomics, functionality and usability. The unit has been divided into an upper and lower module for ease of transport and serviceability. The interface between the control unit and applicator, further described in Section 11.2, has been improved to be an all-in-one connection. The umbilical support arm for the applicators was modified to improve ergonomics (see Section 12 for photographs).

Modifications to the electronics include

(b)(4) (b)(4)

(b)(4) (b)(4)

The touch screen, which provides the graphical user interface to operate the system, has also been enlarged and improved. The touch screen consists of a color display that

allows set-up and viewing of the treatment parameters, warnings, and errors. An audible tone occurs whenever a button on the touch screen is pressed. Furthermore, both an audible tone occurs and visual cues are displayed when a system error is detected. During use, the device displays the current treatment profile and the remaining treatment time on the user interface screen. The labeling in Section 12 illustrates touch screen appearance and user interactions.

The system also includes a pager (usage is optional) to provide audible and readable messages to the clinician. Messages are designed to alert the clinician when:

- The system start up is complete;
- The patient's treatment application is complete or is about to complete;
- The patient's treatment application has been cancelled;
- A call button has been pressed (the new patient call functionality to improve patient/operator interaction during the procedure); or
- A system error has occurred.



Figure 2: Control Unit

11.2. ZELTIQ BREEZE APPLICATOR

The hand-held applicator comes in two styles : a belt applicator (Figure 3) and a vacuum applicator (Figure 4).

The applicator applies controlled cooling and warming to the treatment site through panels of thermoelectric coolers (TEC). The belt applicator is configurable in arrays of as few as two (b)(4) and the vacuum applicator has two panels. Each TEC panel (b)(4) (b)(4)

(b)(4) (b)(4) (b)(4)

(b)(4) (b)(4)

control unit to each of the links in the applicator. As a safety feature, TEC power will be removed from the applicator if an electrical short is detected.

Applicators connect to the control unit by a flexible cable and a modified all-in-one connection (Figure 5). The cable incorporates the tubing for liquid exchange (chiller fluid) between the TECs and the chiller housed in the control unit. The cable also houses the electrical connections and vacuum tubing. The all-in-one connection is the interface between the applicator and the control unit; its use is described in the labeling in Section 12.

The chiller fluid removes excess heat from the TECs in applications involving skin cooling; the TECs control the amount of heat removed through the skin.

In addition to cooling and heating, the applicators can deliver vibratory (belt) or pulsatile (vacuum) massage to the treatment site. When in use, the belt applicator provides vibrational massage that propagates from the center of the applicator through the links of the belt into the skin and underlying tissue. The vacuum applicator provides pulsatile massage by cycling the vacuum pressure which holds the tissue in place within the applicator during treatment.

The articulated belt applicator is designed to conform to the curvature of the body and to be strapped onto the desired application site.

The vacuum applicator draws the skin up between two independently controlled TEC panels; vacuum is maintained to hold the tissue in place during treatment. The design has been modified to remove the flexible cup, incorporating it into the vacuum sleeve described in Section 11.3.

The top of each applicator is equipped with control buttons as an optional method to initiate or terminate treatment. In the case of the vacuum, this includes controls to start and stop the vacuum pump.



Figure 3: Belt Applicator. Left: Top view of Belt Applicator showing control panel. Right: Bottom view of Belt Applicator showing thermoelectric cooler (TEC) panels (without sleeve attached).



Figure 4: Vacuum Applicator. Left: Top view of Vacuum Applicator showing control panel. Right: Bottom view of Vacuum Applicator showing thermoelectric cooler (TEC) panels.

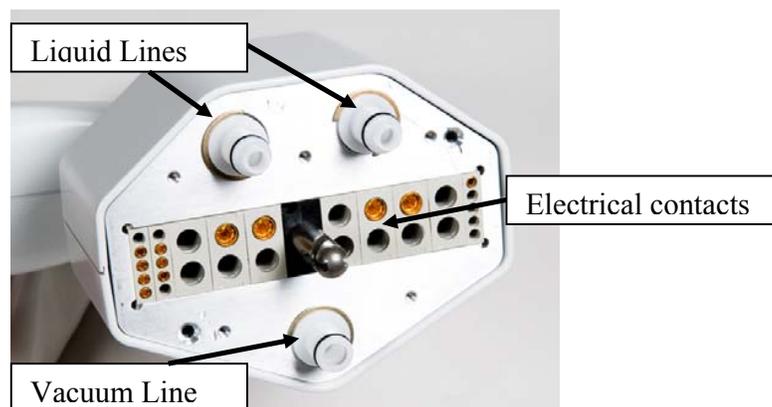


Figure 5: All-in-One Connector



Figure 6: Belt Sleeve

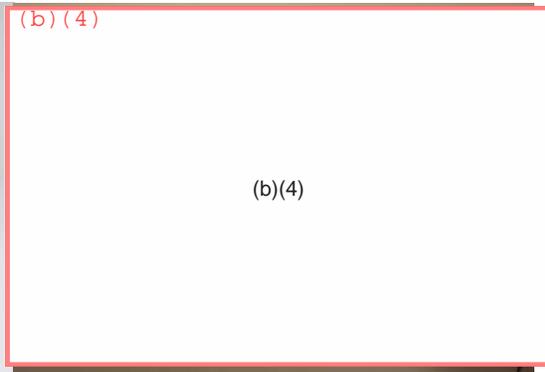


Figure 7: Vacuum Sleeve

11.4. SOFTWARE

The control unit software provides the user interface to select a treatment and apply treatment. It controls the chiller and the applicator. The control unit (b) (4)

(b) (4) (b)(4)

The applicator software responds to commands from the control unit to control the applied heat

(b) (4) (b)(4)

treatment to start and continue. Secure processors have been incorporated into the design of the Control Unit, applicators and sleeves to enhance this communication, prevent counterfeiting and enforce usage limits.

The improved algorithm is similar to the Zeltiq CLN1 Dermal Cooling Device whereby both devices (b) (4) (b)(4) the TEC power. The difference be

(b) (4) (b)(4)

Vacuum pressure is now adjusted using the graphical user interface and the software governs the highest setting, an improvement over the manual control in CLN1 dermal cooling.

The software was updated to support the enhanced graphical user interface and new patient call functionality that works in conjunction with the optional paging system to improve operator/patient interaction. Finally, error handling / logging has been modified to improve the usability and serviceability of the device. More details on the patient call functionality are provided in the user manual included in Section 12.

The optional paging Device, provides a secondary system to notify staff of system status such as: when a treatment session is cancelled, procedure completion or system error. Customers may choose to disable use of the paging system without impact to system functionality or safety. The paging system consists of:

- The control unit, which collects and formats monitoring data to send to the transmitter via an RS232 port;
- A transmitter (b) (4) (b)(4) that is located in the control unit, transmits its messages via UHF frequency (420 – 470 MHz) and modulation; and
- An alphanumeric pager (b) (4) (b)(4) that receives messages from the transmitter.

11.5. ZELTIQ GELPAD AND ZELTIQ GEL

The Zeltiq Gel facilitates thermal contact of the device during minor variances in device-to-skin contact. Zeltiq Gel (b) (4) (b)(4) with

(b) (4)
(b)(4)

The Zeltiq Gelp K080118. The (b) (4) (b)(4)
(b) (4) (b)(4)
(b) (4) (b)(4)

11.6. DEVICE OPERATION

Complete instructions for use and principles of operation for the Zeltiq System can be found in the labeling referenced in Section 12. The following briefly outlines the steps for the procedure:

- The clinician applies a gelpad to the site under treatment.
- The clinician then attaches a sleeve to the applicator and selects the treatment profile via the touch screen.
- The applicator can then be applied to the treatment area.
- Once a treatment profile is selected by the user and the treatment started, the applicator CIF is automatically set and maintained by the control software based on the treatment profile selected.
- The CIF of the TEC panels, as monitored by the sensors in the applicator and the sleeve, will be maintained for the pre-set duration. During treatment, as a safety feature, the

(b) (4) (b)(4)
(b) (4)
(b)(4)

- (b) (4) (b)(4) treatment profile, the controller will automatically shut the TEC panels off.

11.7. INTENDED USE

There is no change to the intended use of the device.

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and / or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

(b) (4)
(b)(4)

12. PROPOSED LABELING

Table 4 contains the labeling and instructions for use for the components of the Zeltiq System, indexing them by attachment.

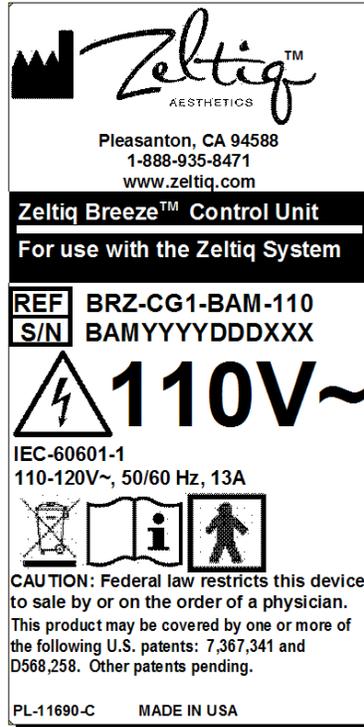
Table 4: Device Labeling		
System Component	Device Label	Attachment
Breeze Control Unit	<ul style="list-style-type: none"> • PL 11688, Zeltiq Breeze Control Unit Upper Module Label • PL 11690, Zeltiq Breeze Control Unit 110V System Label 	<ul style="list-style-type: none"> • 12-1 • 12-1
Breeze Applicator	<ul style="list-style-type: none"> • PL 11540, Com1 3L Applicator Label • PL 11544, Com1 Vacuum Applicator Label 	<ul style="list-style-type: none"> • 12-2 • 12-2
AcuCool Belt Sleeve	<ul style="list-style-type: none"> • PL 11589, Com1 3L Sleeve Pouch Label • PL 11590, Label, Box, 3L Com1 Sleeve • PL 11591, Label, Shipper, 3L Com1 Sleeve 	<ul style="list-style-type: none"> • 12-3 • 12-3 • 12-3
AcuCool Vacuum Sleeve	<ul style="list-style-type: none"> • PL 11584, Label, Inner Pouch, V3, Com1 Sleeve • PL 11587, Label, Shipper, V3 Com1 Sleeve 	<ul style="list-style-type: none"> • 12-4 • 12-4
Gels	<ul style="list-style-type: none"> • PL 10909, Zeltiq Gel Bottle Label • PL 11594 Label, Box of 6, Gel Bottles 	<ul style="list-style-type: none"> • 12-5 • 12-5
Gelpads	<ul style="list-style-type: none"> • PL 11478, Gelpad Label • PL 11480, Gelpad Carton Label 	<ul style="list-style-type: none"> • 12-5 • 12-5
System Component	Directions for Use	
Overall System User Manual	PL 12689, User Manual, Zeltiq System	12-6
Sleeve	<ul style="list-style-type: none"> • PL 11822, DFU, Zeltiq AcuCool Belt Sleeve • PL 11837, DFU, AcuCool Vacuum Sleeve, V3 	<ul style="list-style-type: none"> • 12-7 • 12-8
Gelpads	PL 11940, Gelpad Directions for Use	12-9

The device labels have changed to reflect the name changes to the new model.

The directions for use (DFUs) have undergone a comprehensive change to improve their readability and usability. Detailed changes to the DFUs resulting from the design modifications are outlined in Table 5.

Table 5: Changes in the Proposed Labeling Result from Modifications		
Component	Enhancements	Relevant DFU section
Zeltiq Breeze Control Unit (incl. software)	<ul style="list-style-type: none"> Improved industrial design of unit Redesign umbilical support arm for improved ergonomics Separable upper and lower modules Increased size of touch screen display Integrated (all-in-one) interface between control unit and applicator (b)(4) (b)(4) (b)(4) ble voltage power supply (to support future applicators) (b)(4) (b)(4) user interface – Improved control algorithm – Patient call functionality – Improved error handling 	<ul style="list-style-type: none"> PL 12689, Chapter 1 PL 12689, p. 2-6 PL 12689, pp. 3-5 to 3-10 PL 12689, p. 1-2 PL 12689, p. 2-4 to 2-6 PL 12689, p. 1-8 PL 12689, p. 2-14 NA; transparent to user PL 12689, usage limits p. 2-20 NA; transparent to user PL 12689, p. 1-16, Table 1-3 PL 12689, Appendix A
Zeltiq Breeze Applicator (belt and vacuum)	<ul style="list-style-type: none"> Re-designed vacuum applicator; flexible cup has now been designed into the sleeve Improved electrical interconnect between sleeve and applicator for improved reliability (b)(4) (b)(4) ontrol unit and applicator 	<ul style="list-style-type: none"> PL 11837, Fig. 2 PL 11822, Fig. 2 PL 11837, Fig. 4 PL 12689, usage limits p. 2-22 PL 12689, p. 2-4 to 2-6
Zeltiq AcuCool Sleeve (belt and vacuum)	<ul style="list-style-type: none"> n-patient contact, (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) (b)(4) 	<ul style="list-style-type: none"> PL 11822, Fig. 3 NA; transparent to user PL 12689, usage limits p. 2-20
Zeltiq Gelpad	<ul style="list-style-type: none"> (b)(4) (b)(4) 	<ul style="list-style-type: none"> PL 11940, new DFU to improve usability

Attachment 12-1: Breeze Control Unit Labeling



PL11688-C Zeltiq Breeze Control Unit Upper Module Label



PL11688-B Zeltiq Breeze Control Unit 110V System Label

Attachment 12-2: Breeze Applicator Labeling



PL11540-B Label Com1 3L Applicator Label



PL11544-B Com1 Vacuum Applicator Label

Attachment 12-3: AcuCool Belt Sleeve Labeling



PL11589 Pouch Label



PL11590 Carton Label



PL11591 Shipper Label

Attachment 12-4: AcuCool Vacuum Sleeve Labeling



PL11584 Pouch Label



PL11587 Shipper Label

Attachment 12-5: Gels and Gelpad Labeling

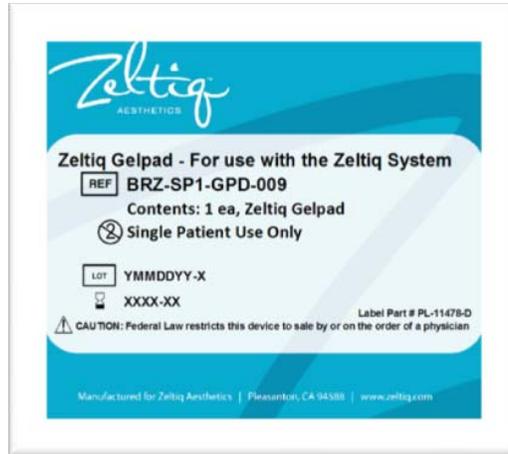


PL10909 Zeltiq Gel Bottle Label

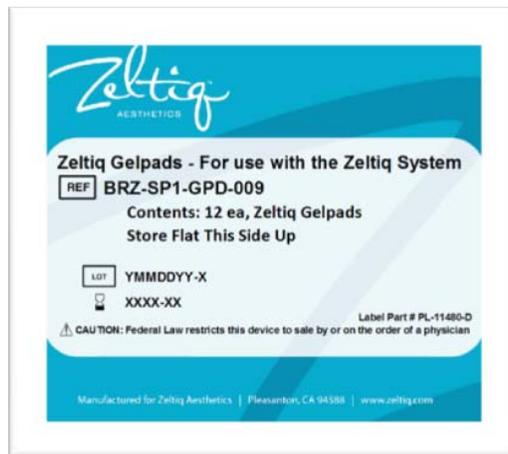


PL11594 Label, Box of 6 Gel Bottles

Attachment 12-5 (cont'd)



PL11478 Gelpad Label



PL11480 Gelpad Carton Label

Attachment 12-6: User Manual, Zeltiq System



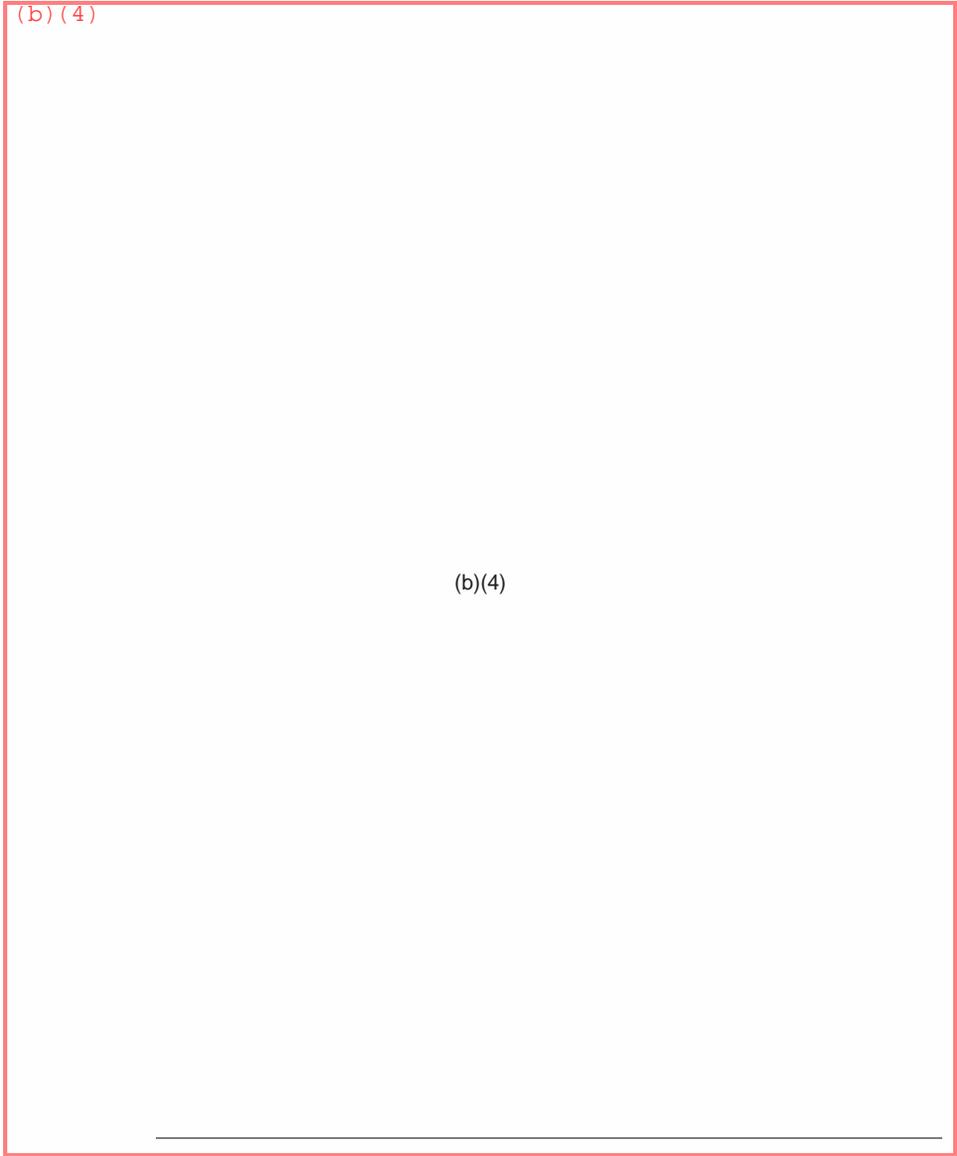
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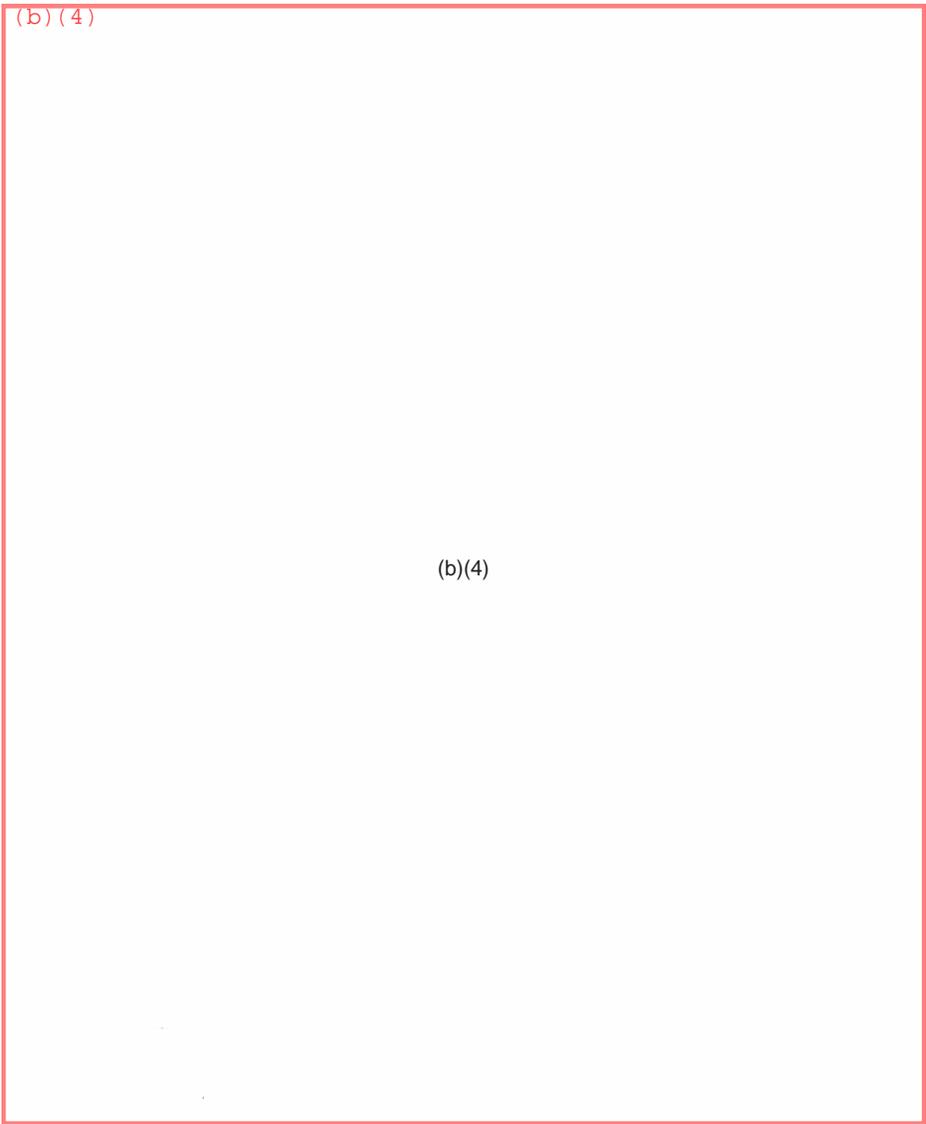
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	Authorized Representative Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands

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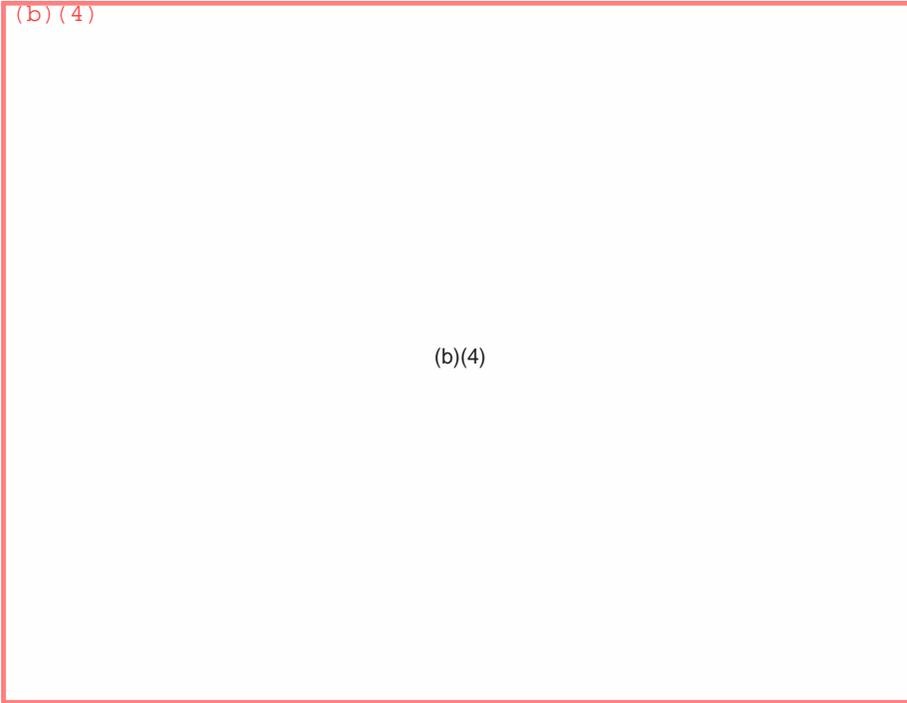
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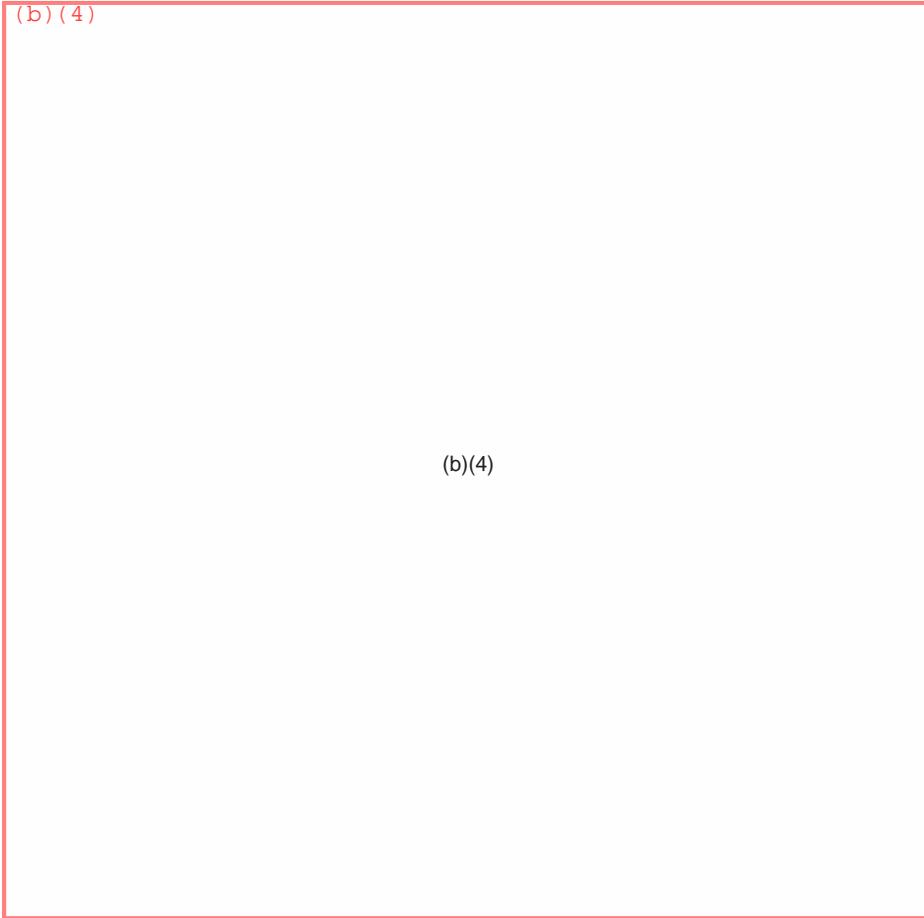


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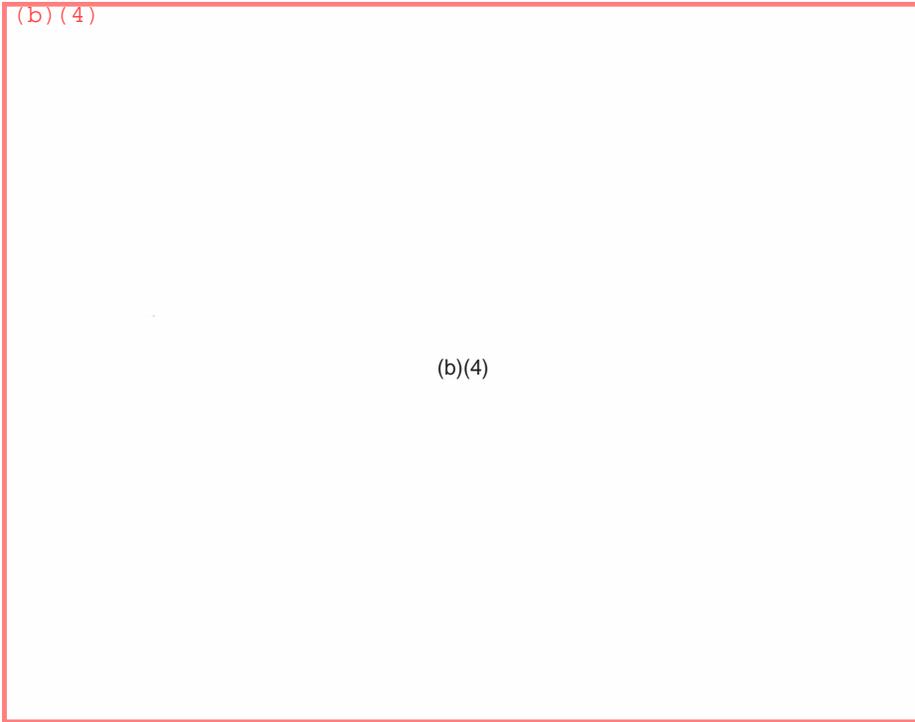


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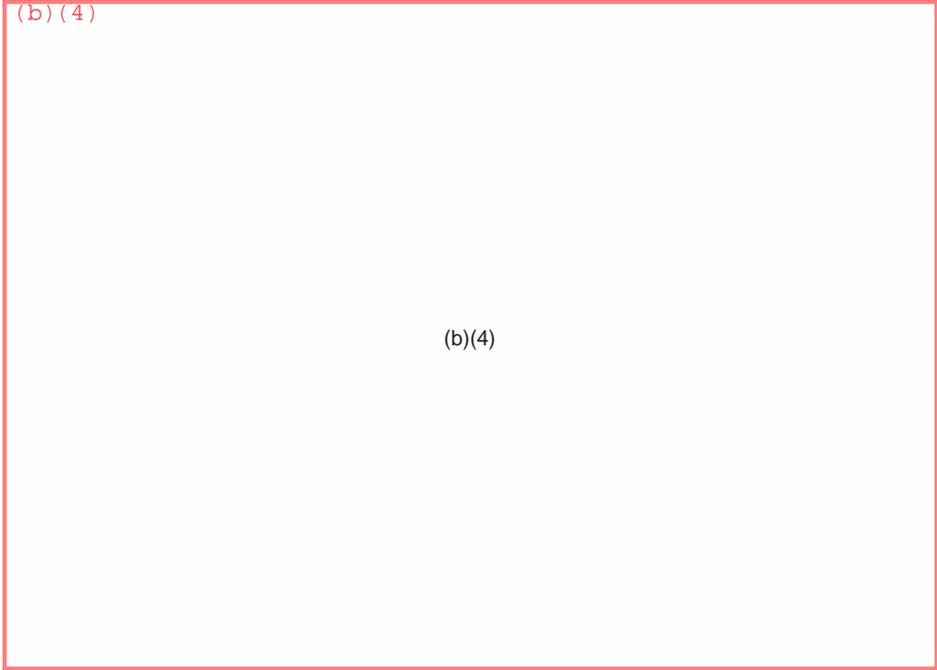
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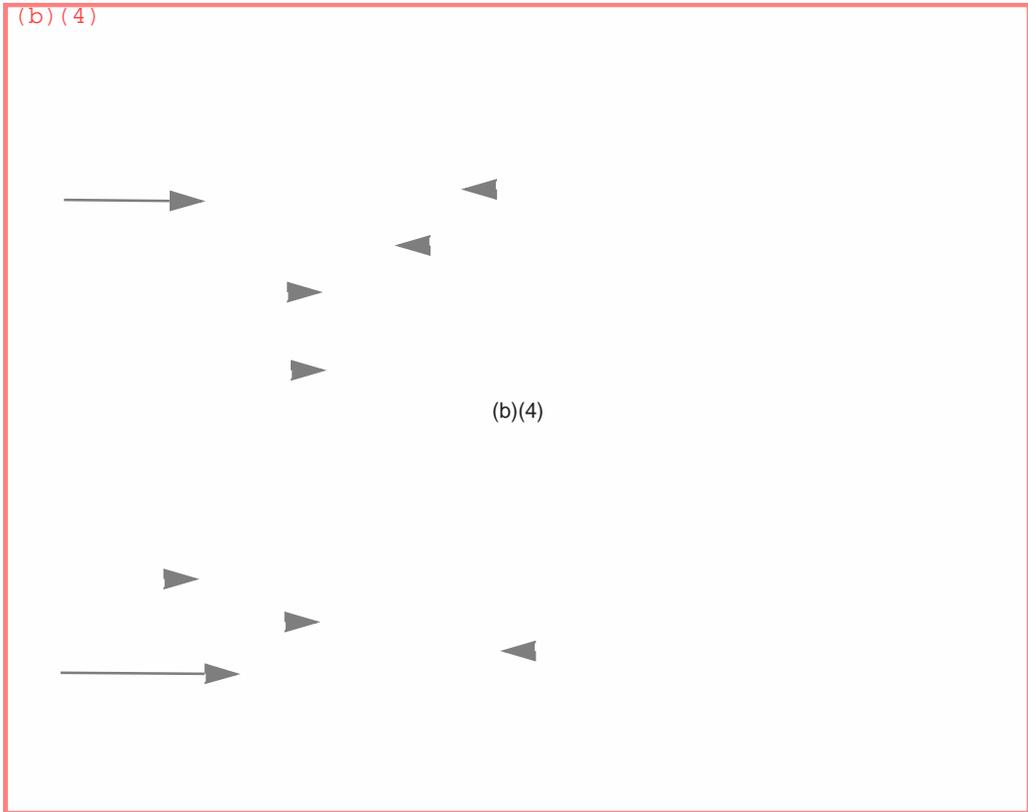


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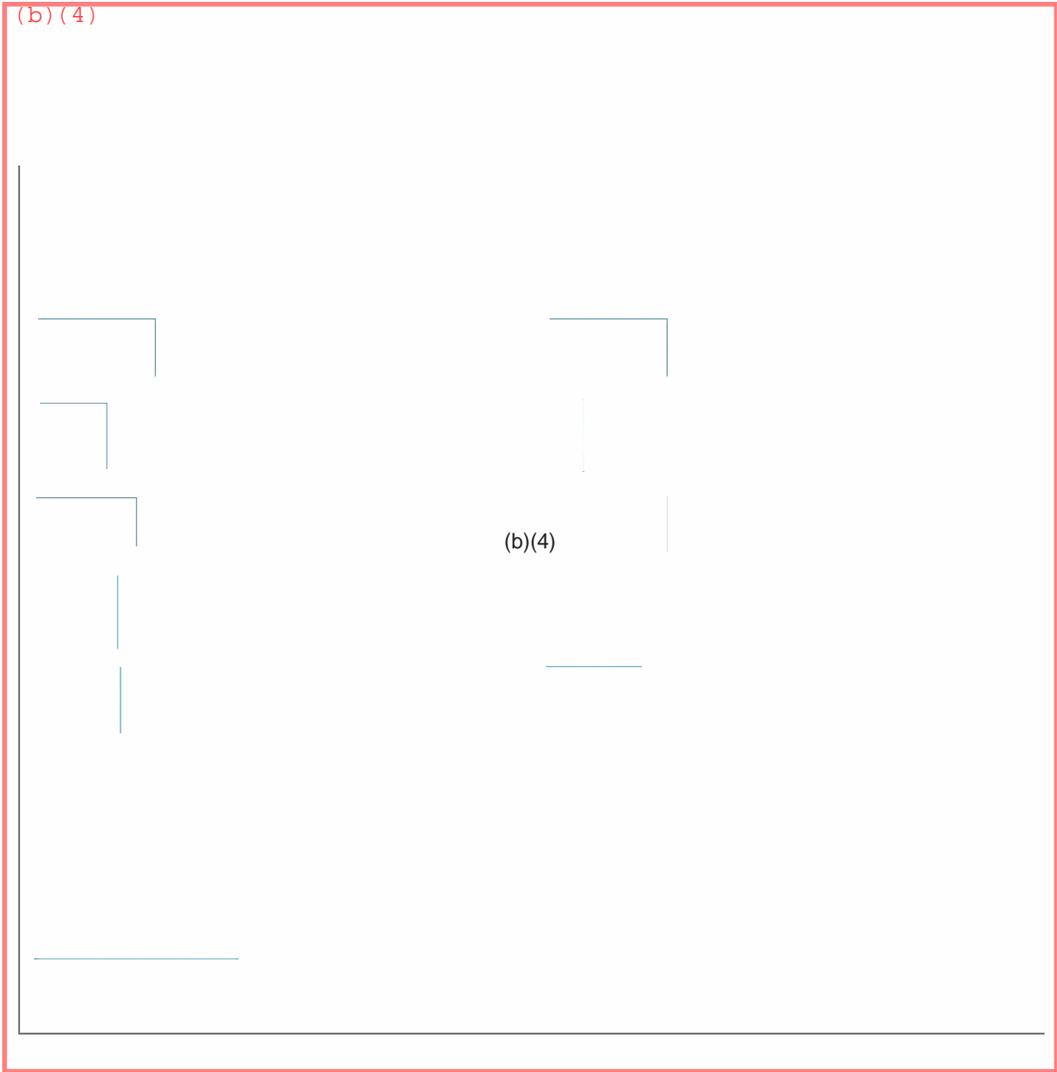
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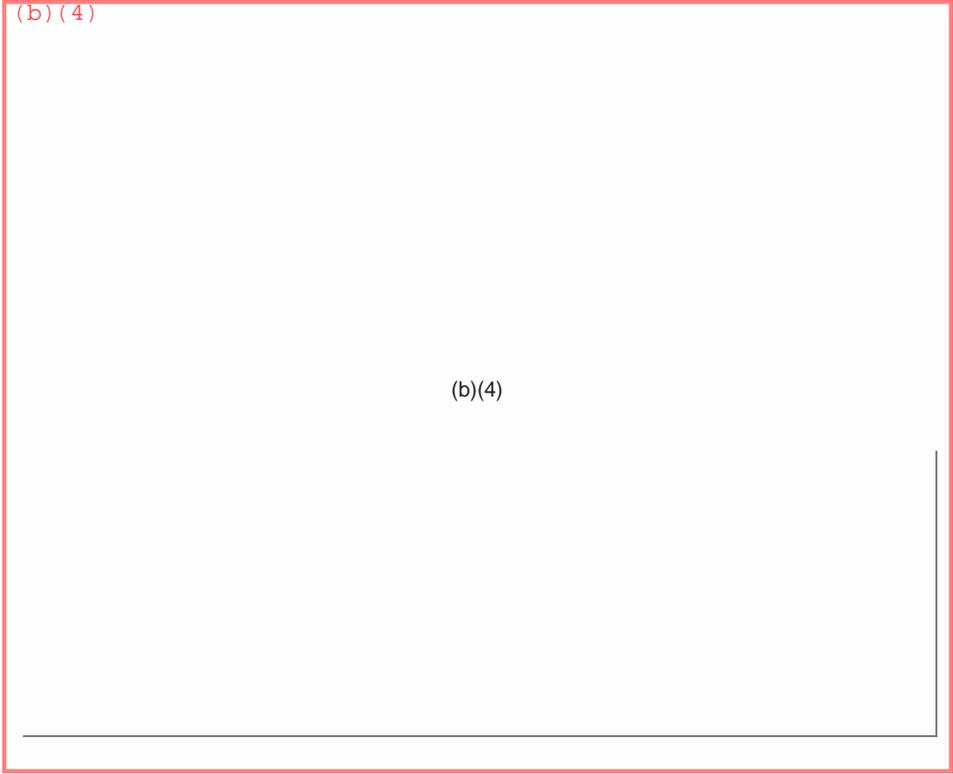




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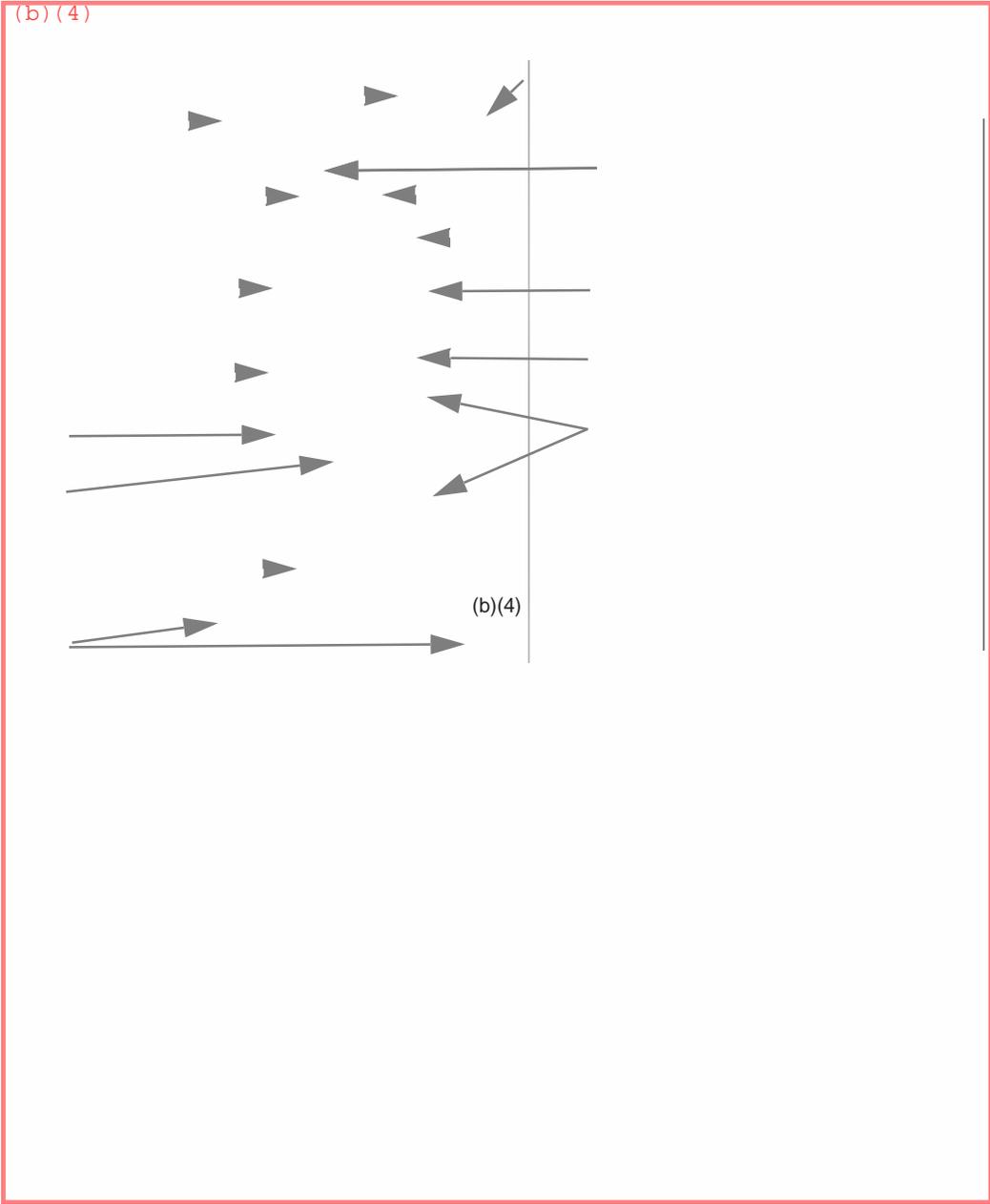
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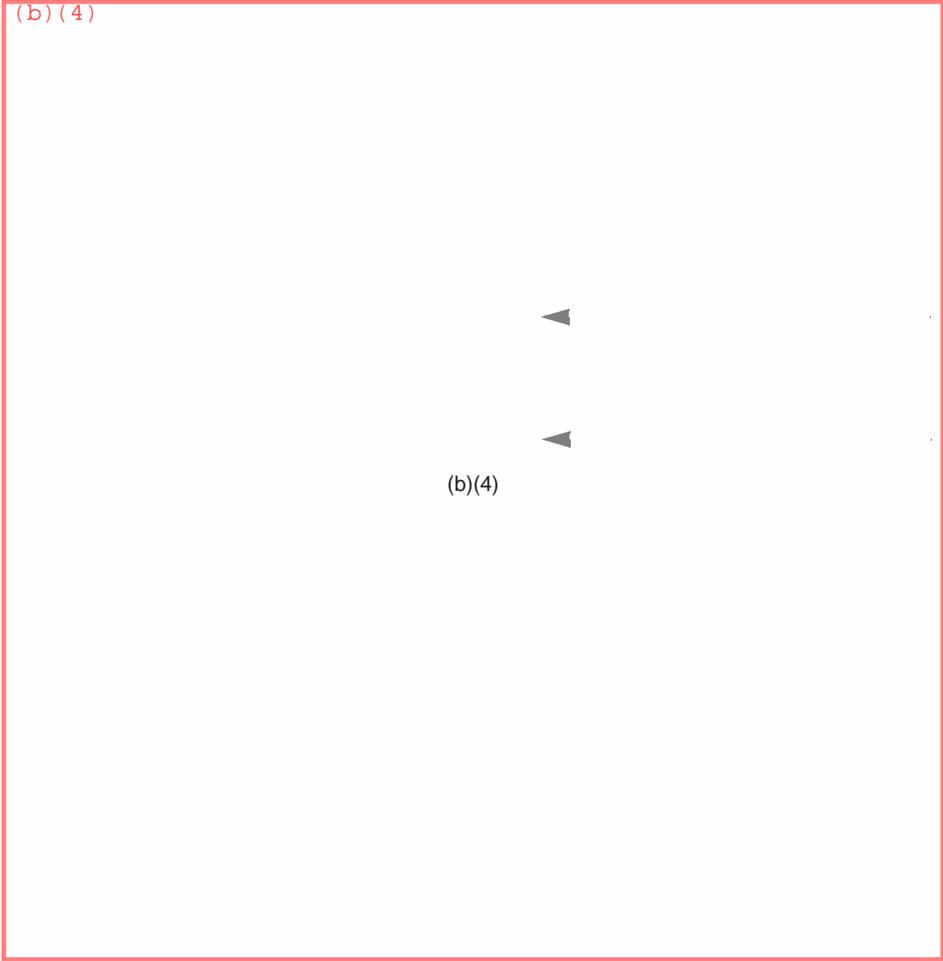




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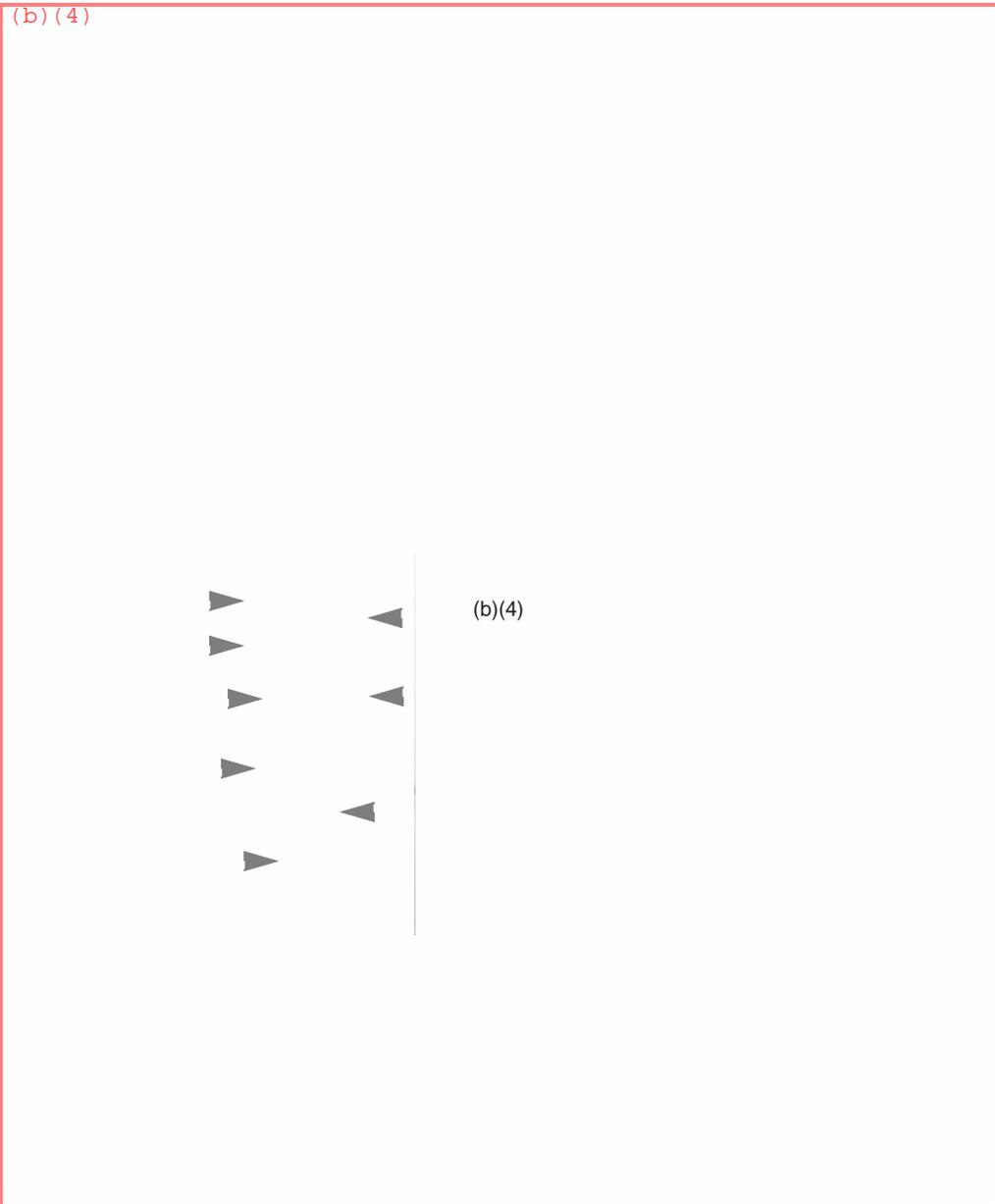
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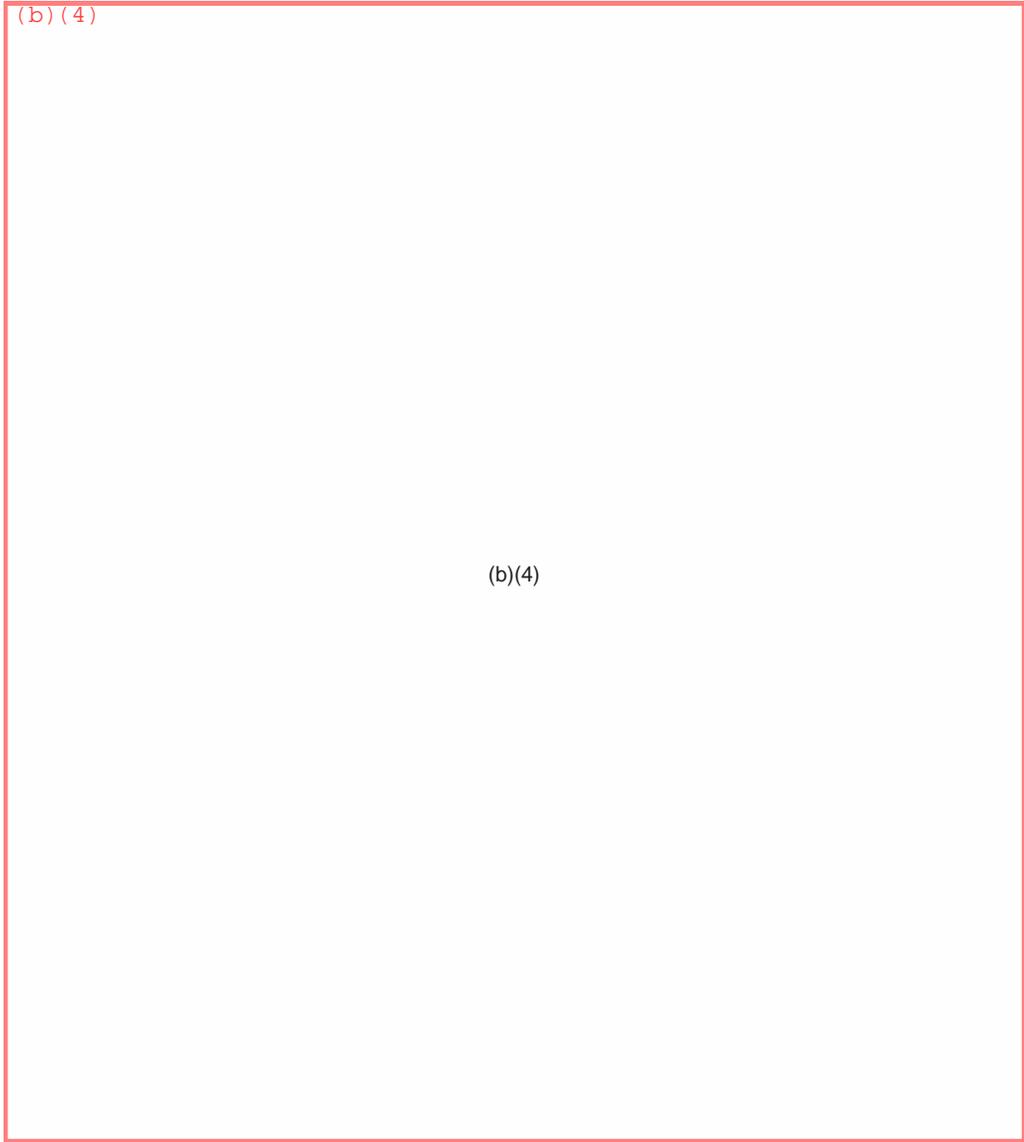




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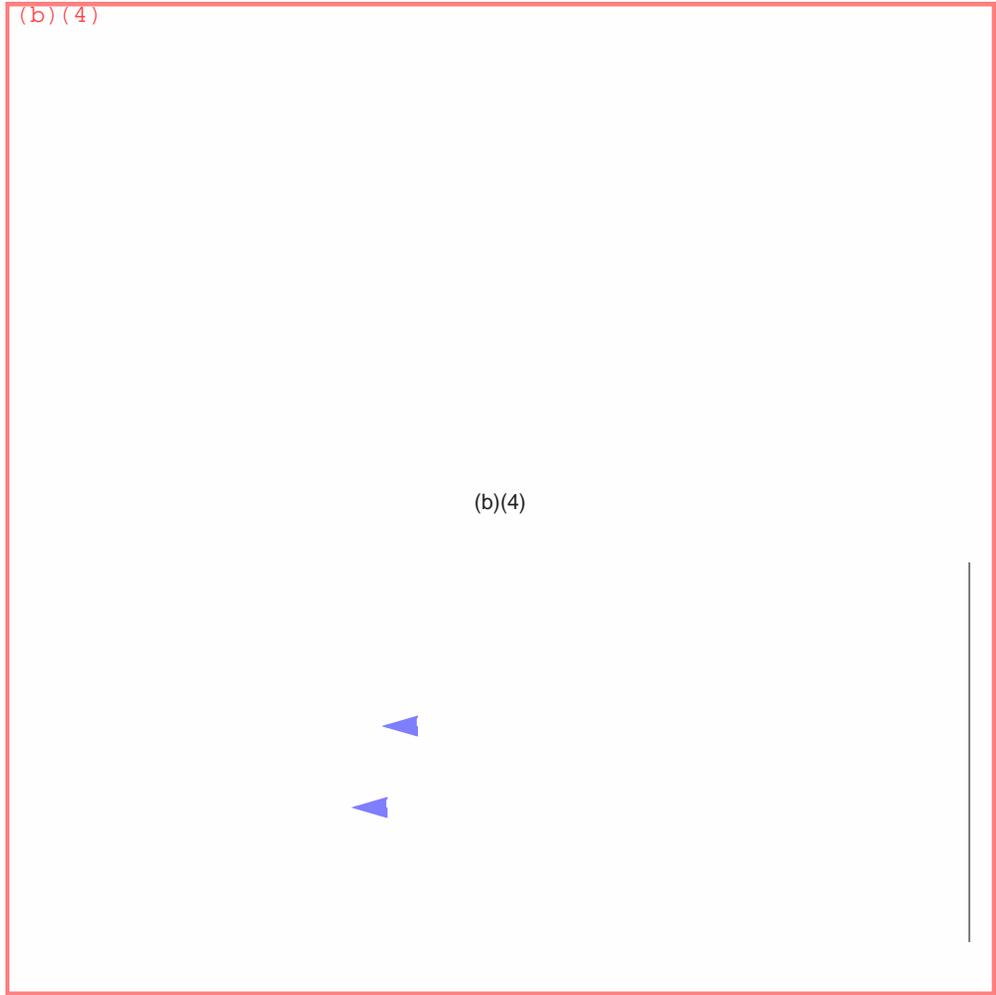




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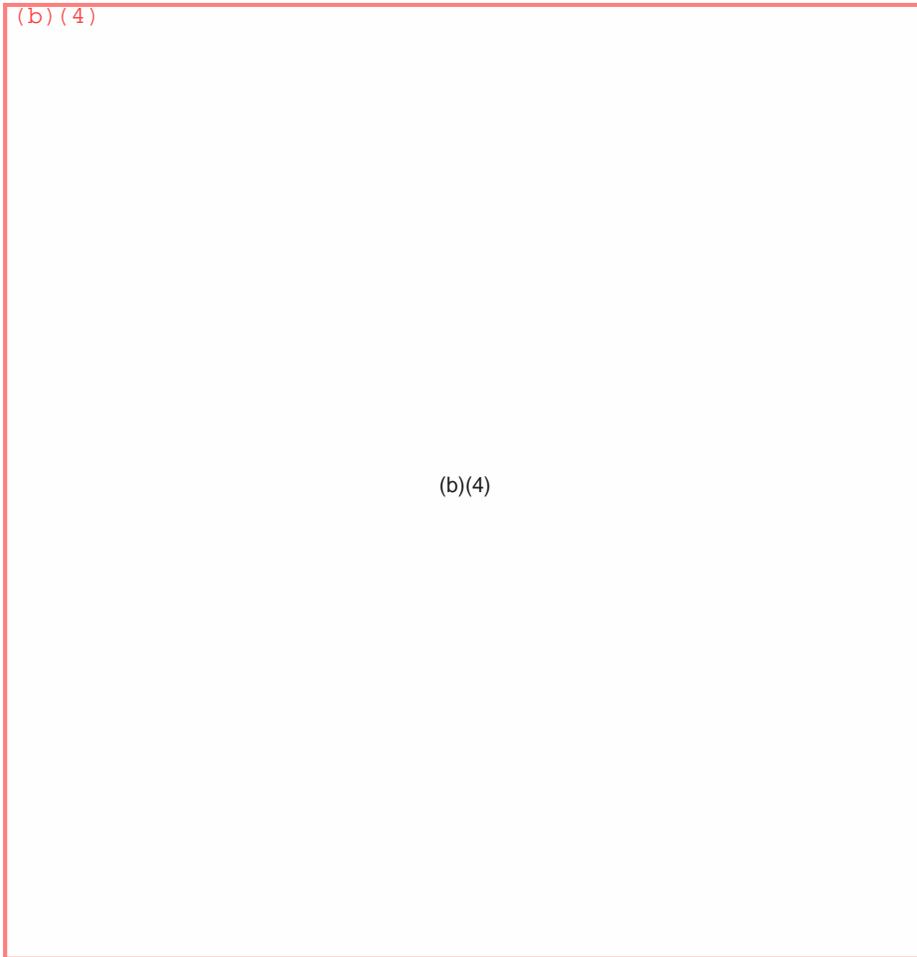
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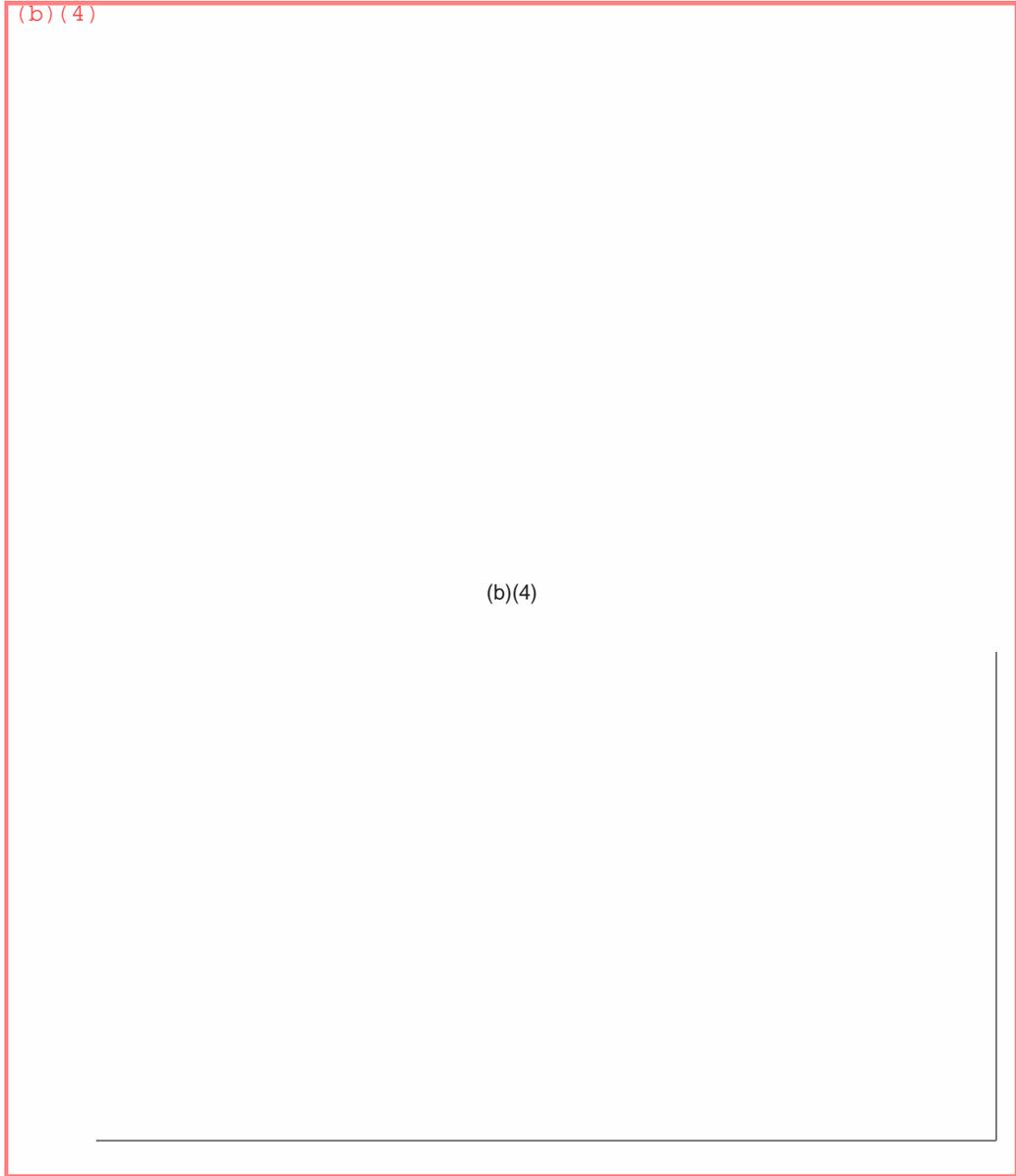




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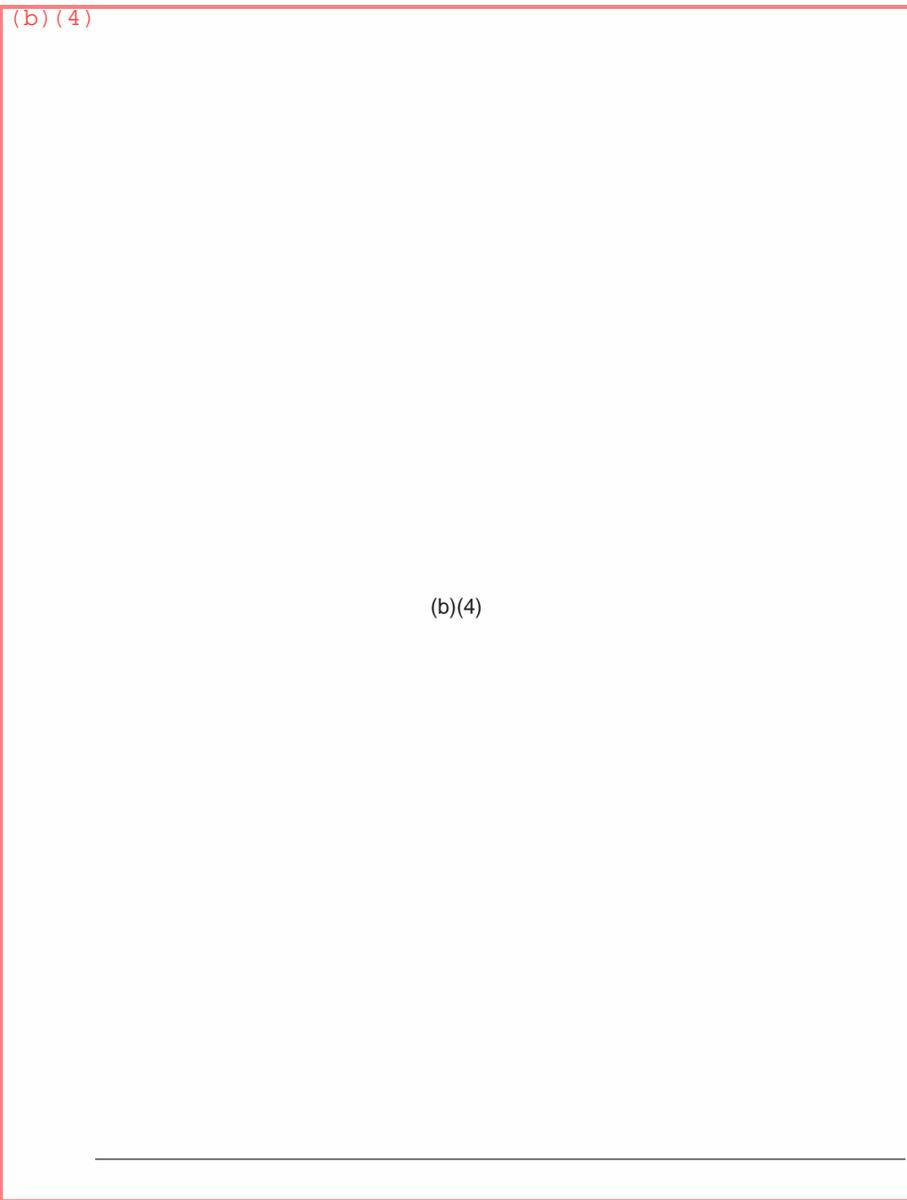
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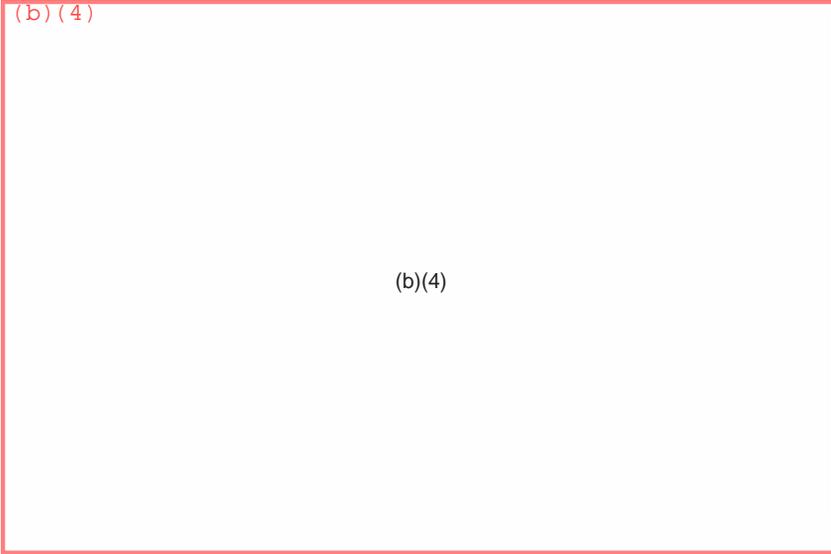




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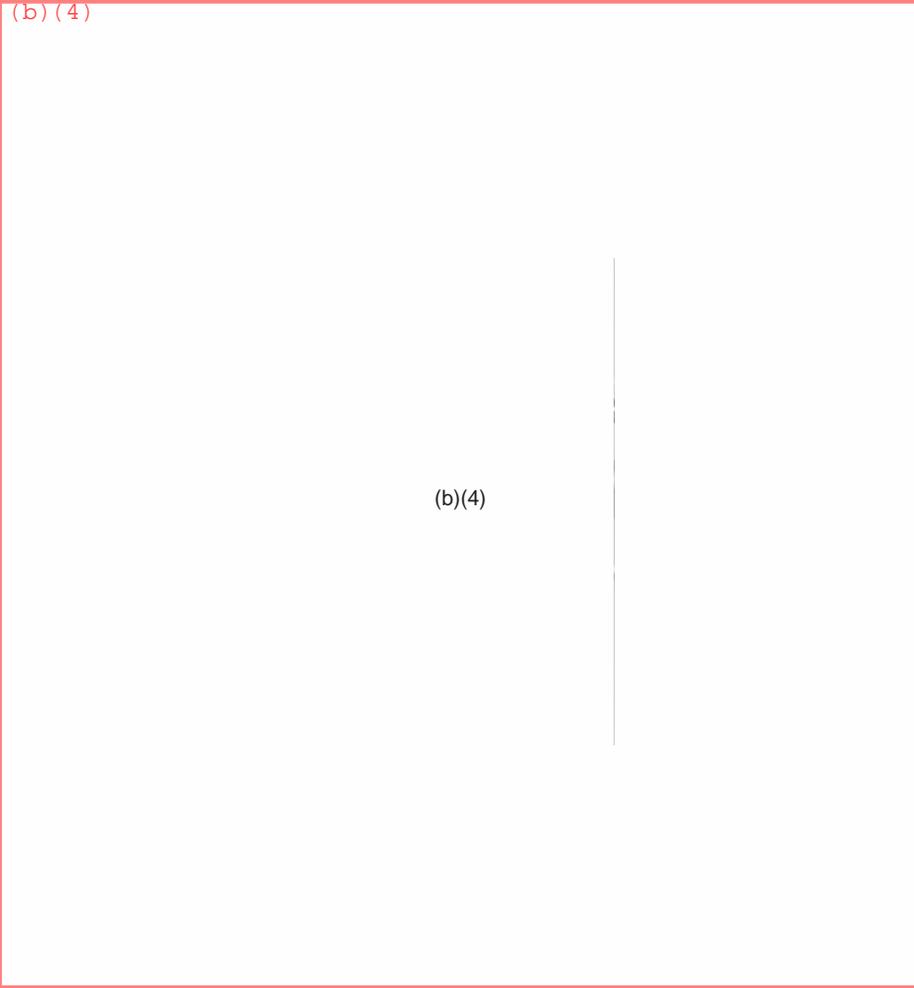
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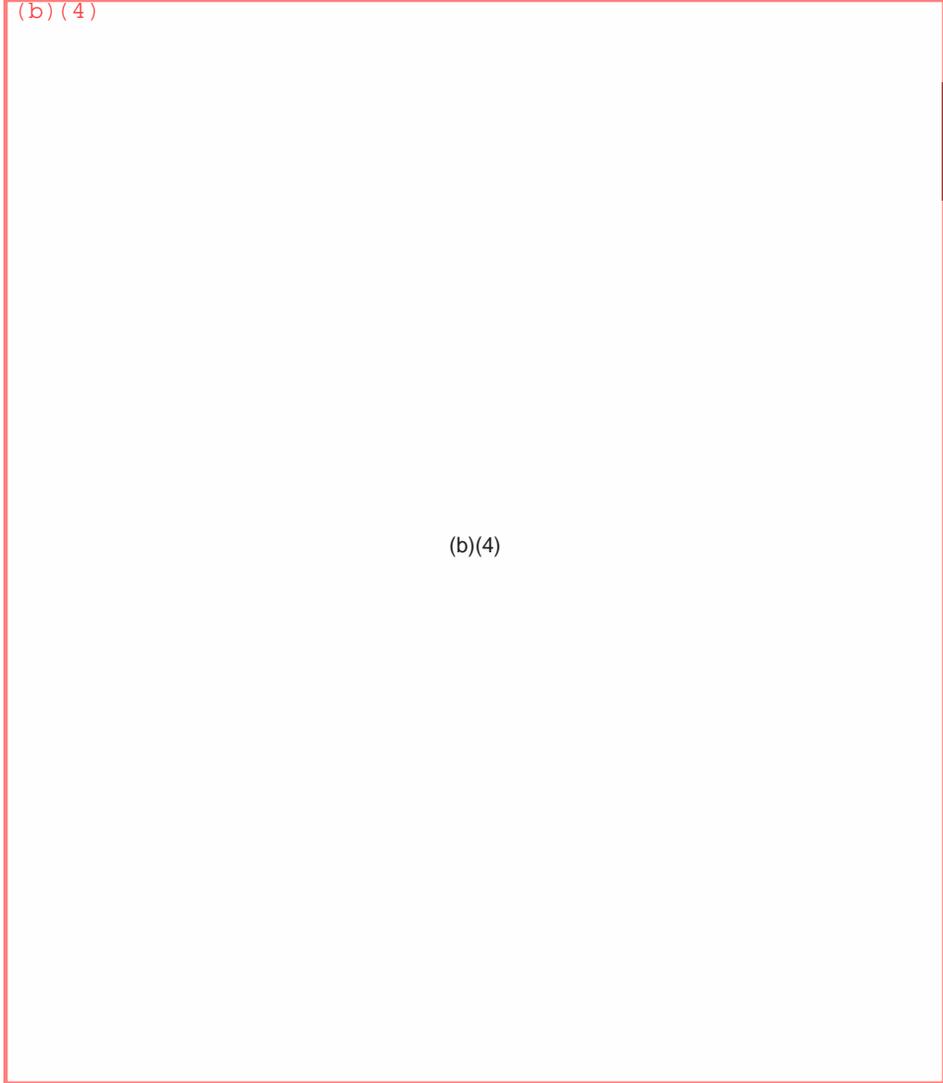




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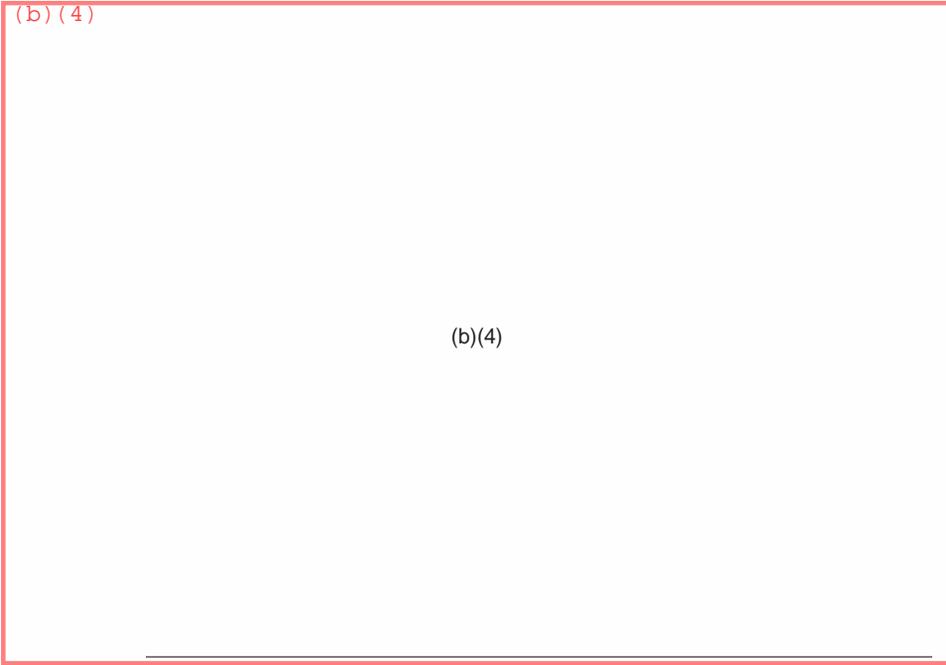
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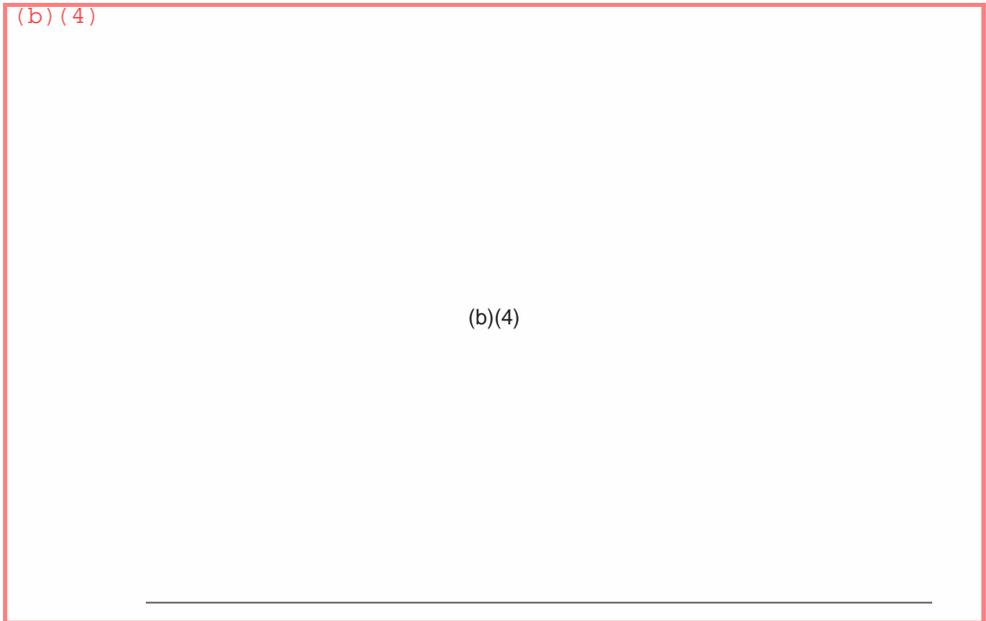


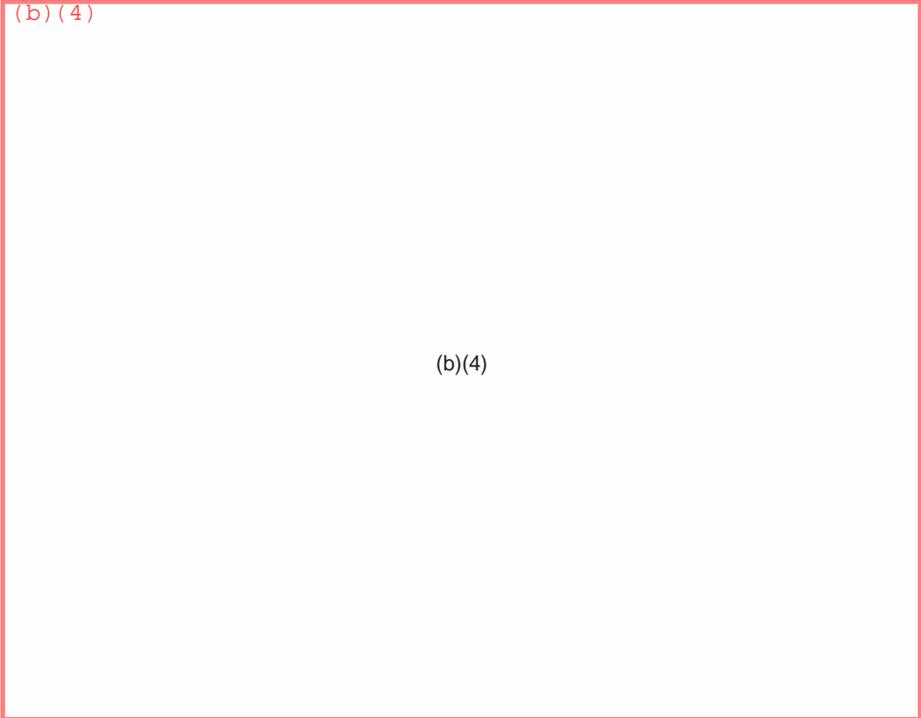
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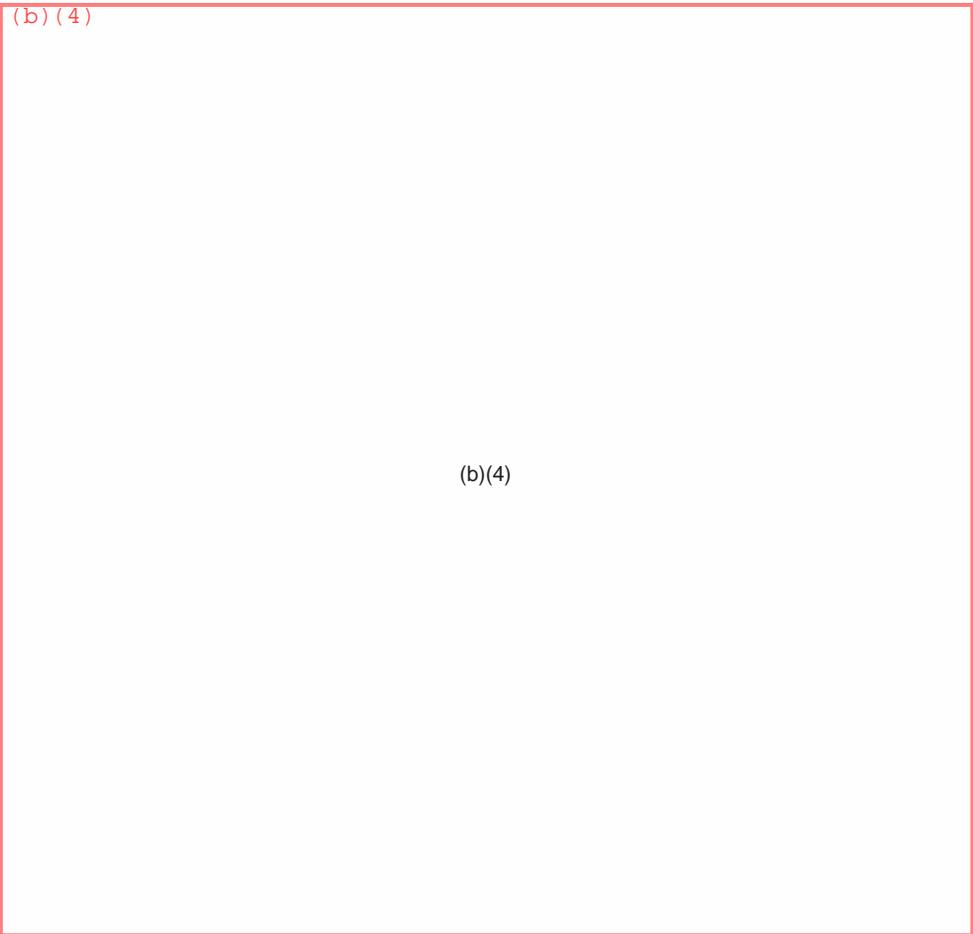
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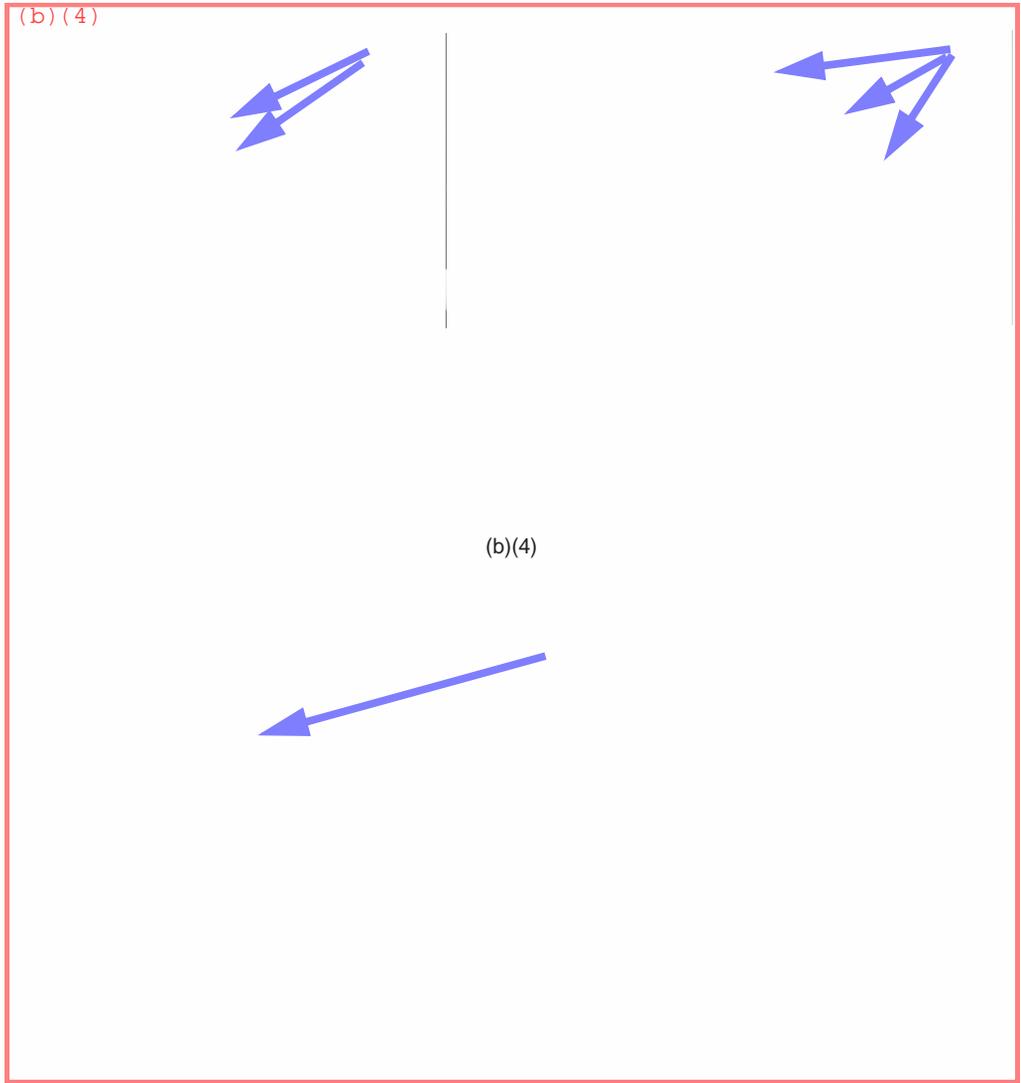




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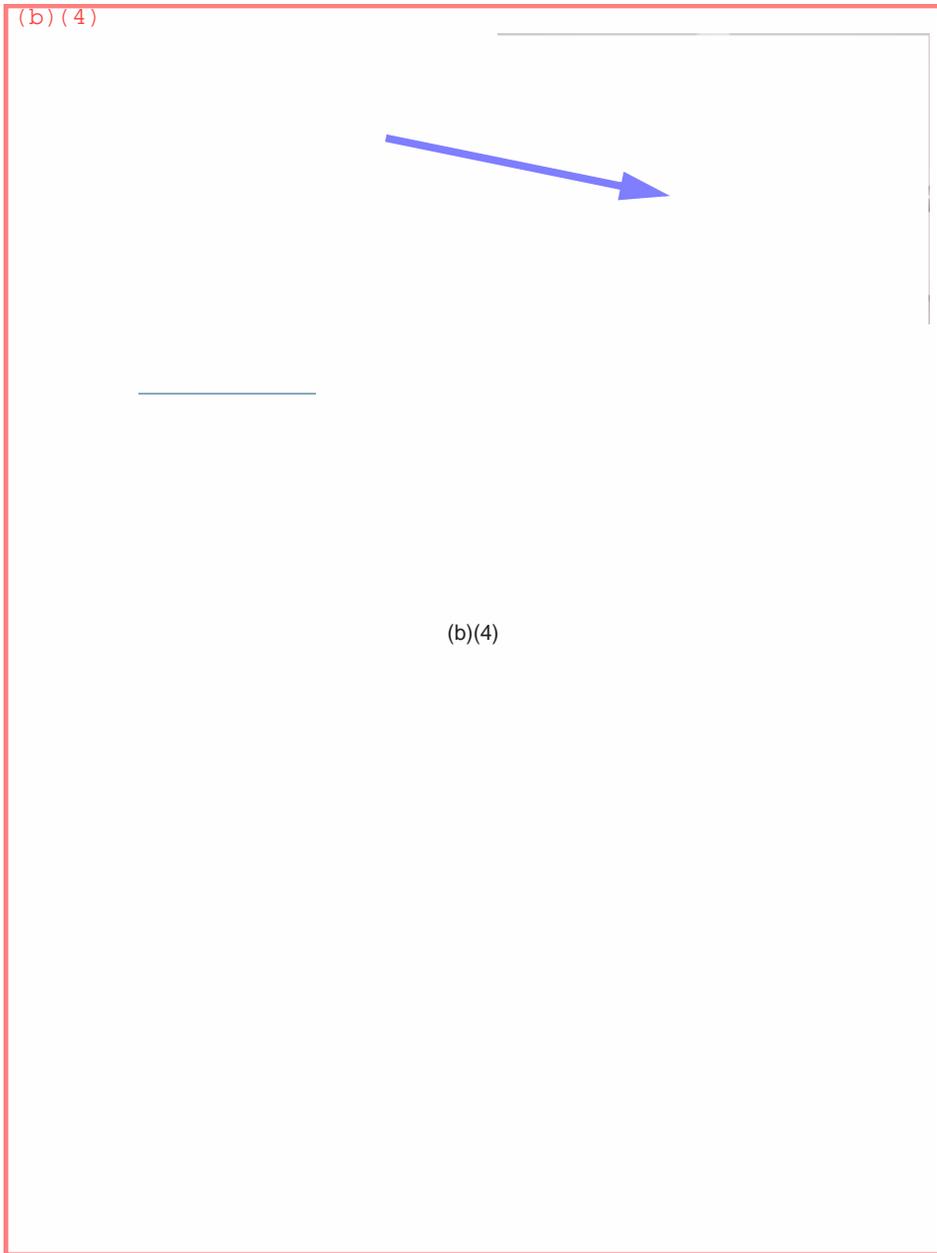
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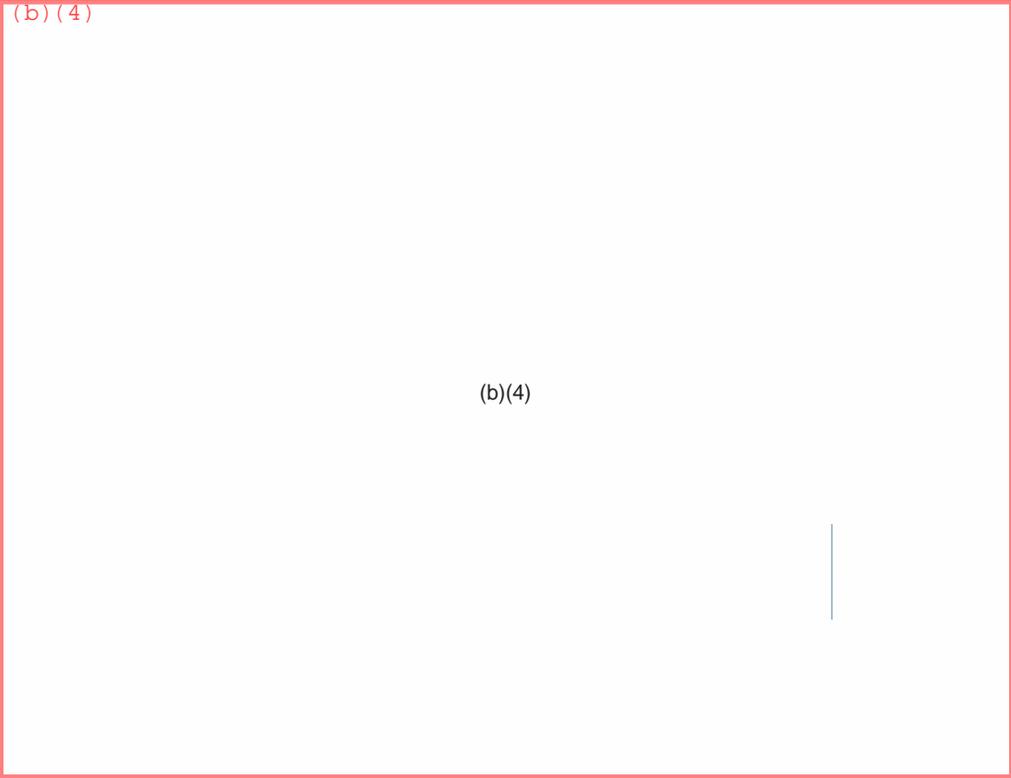




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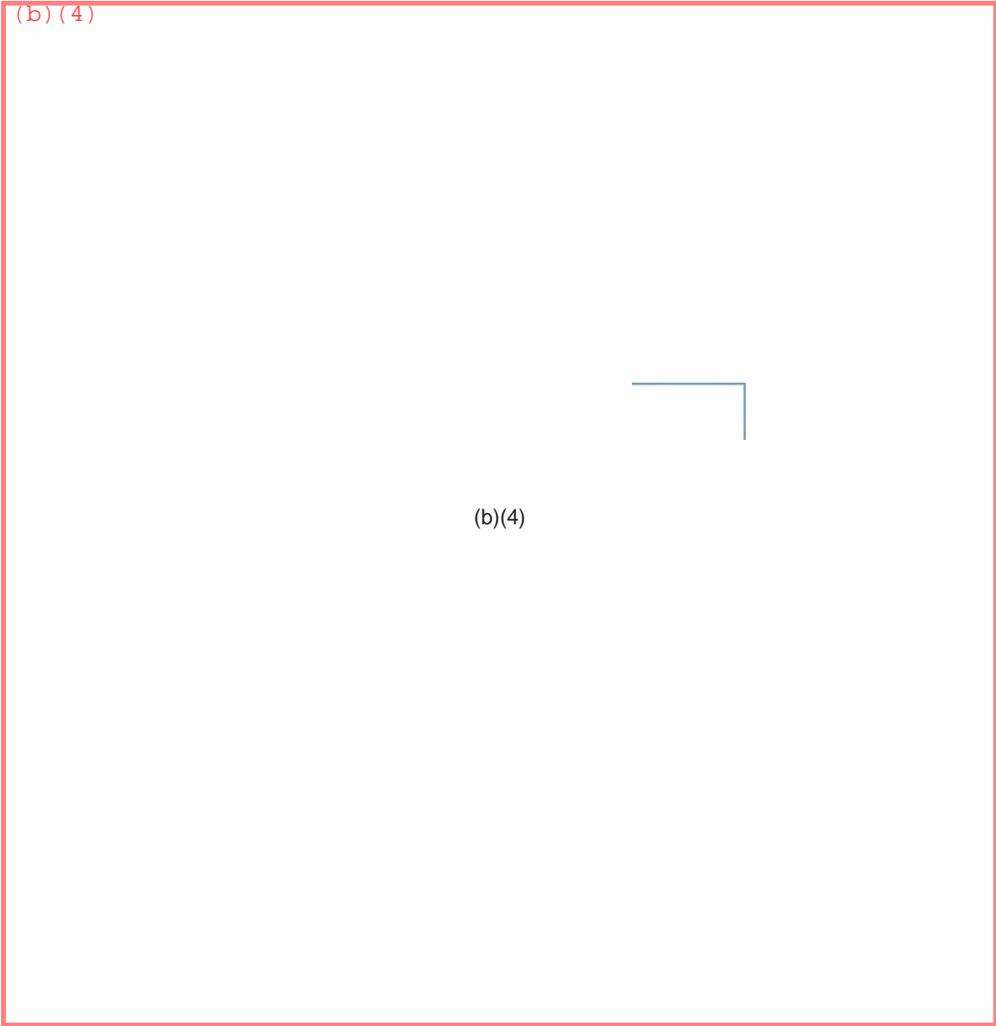
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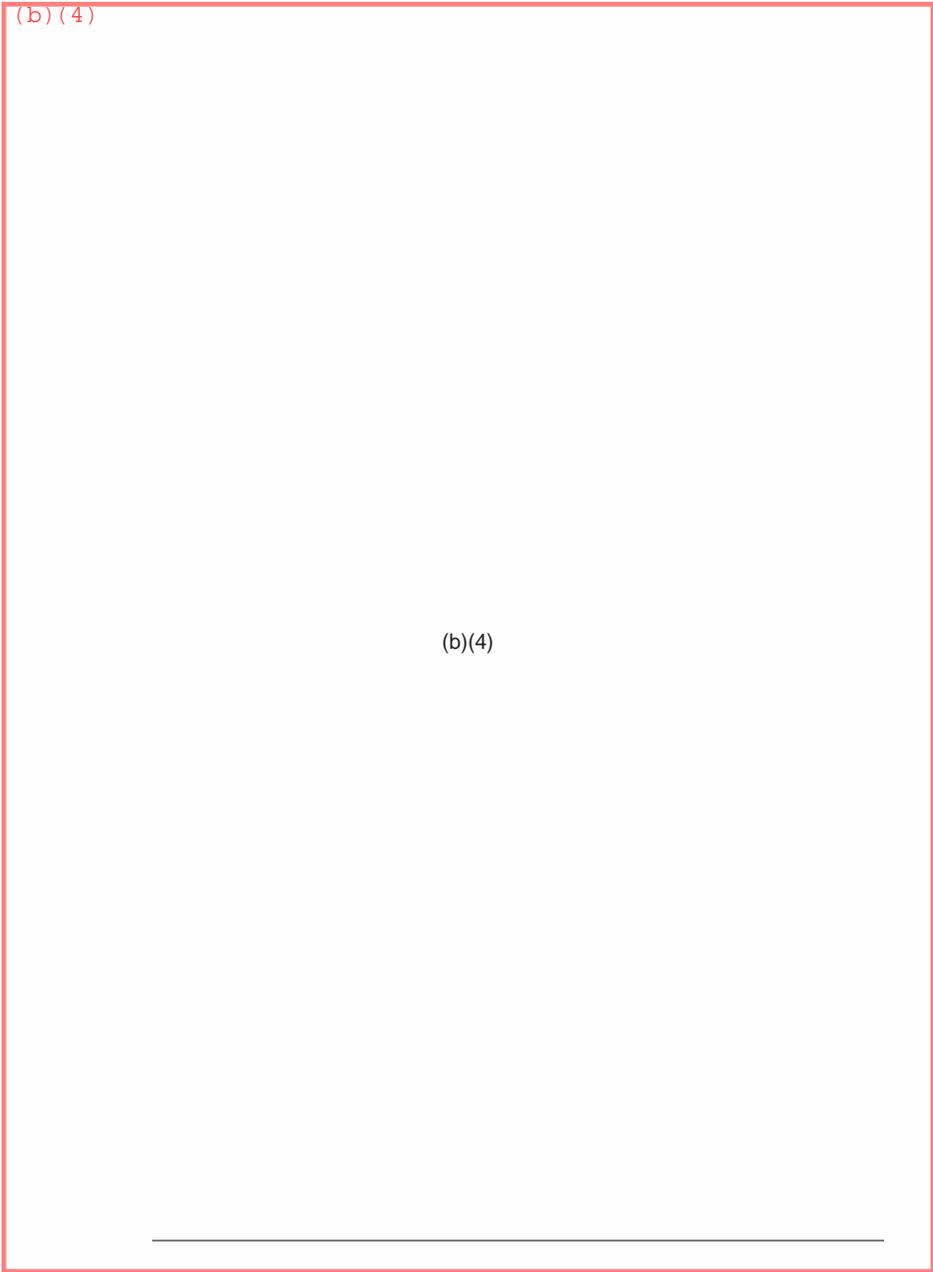




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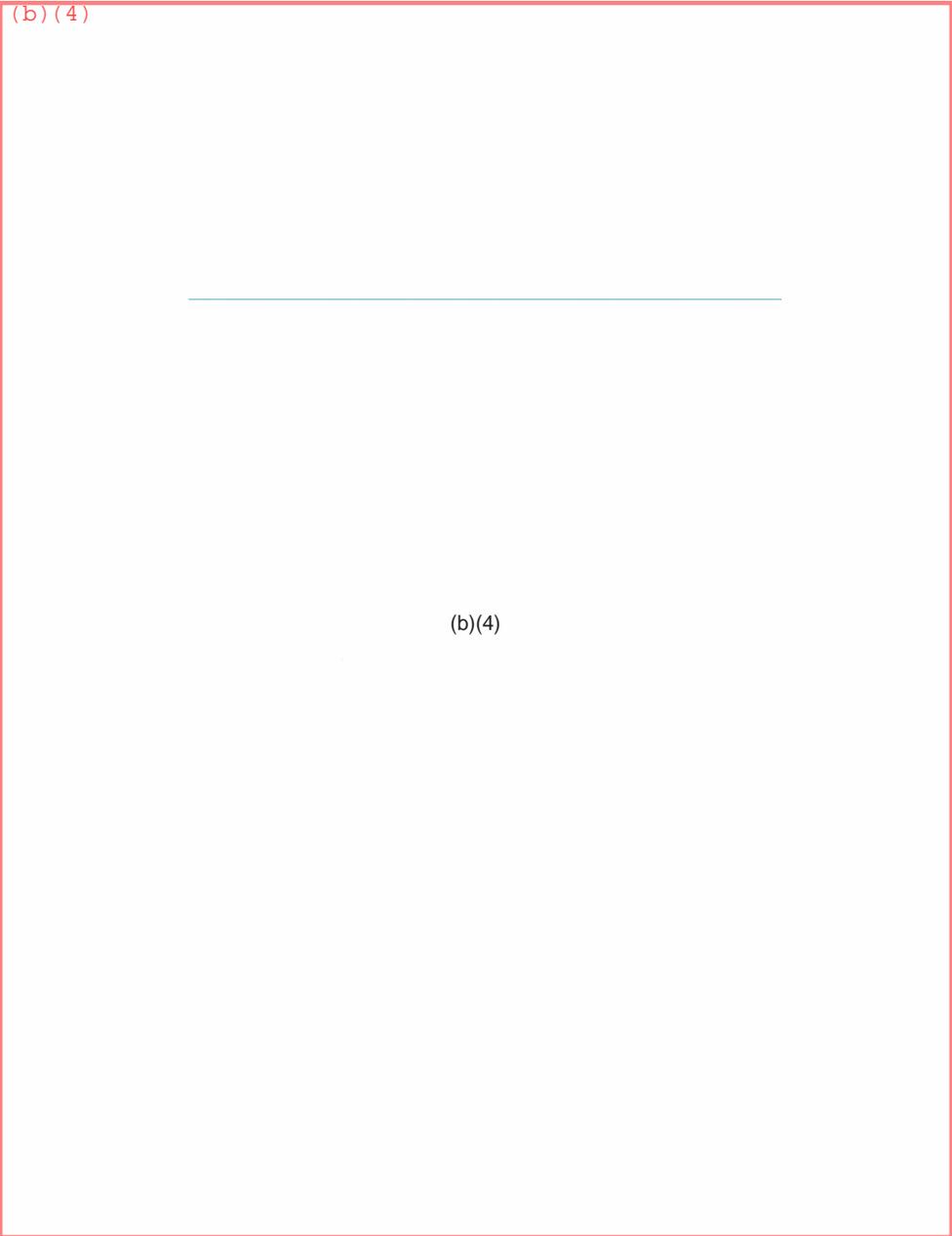
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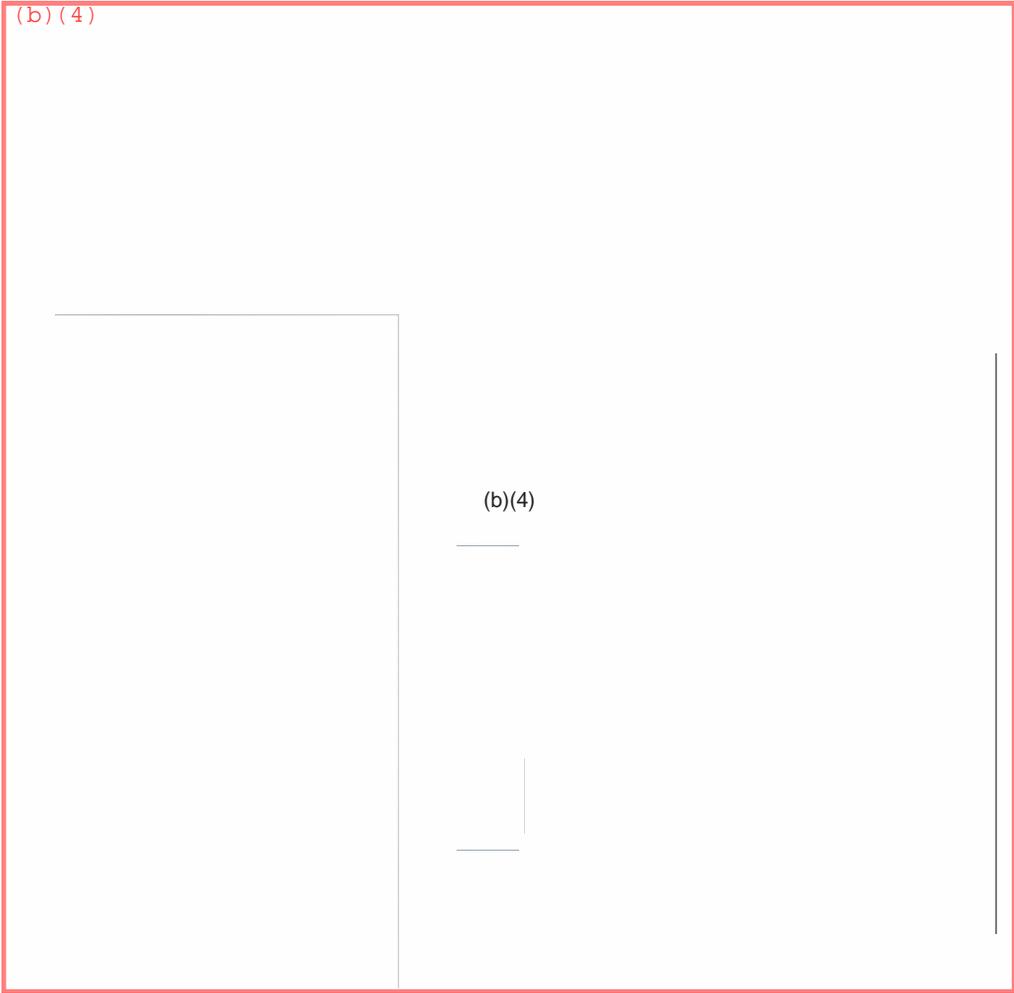
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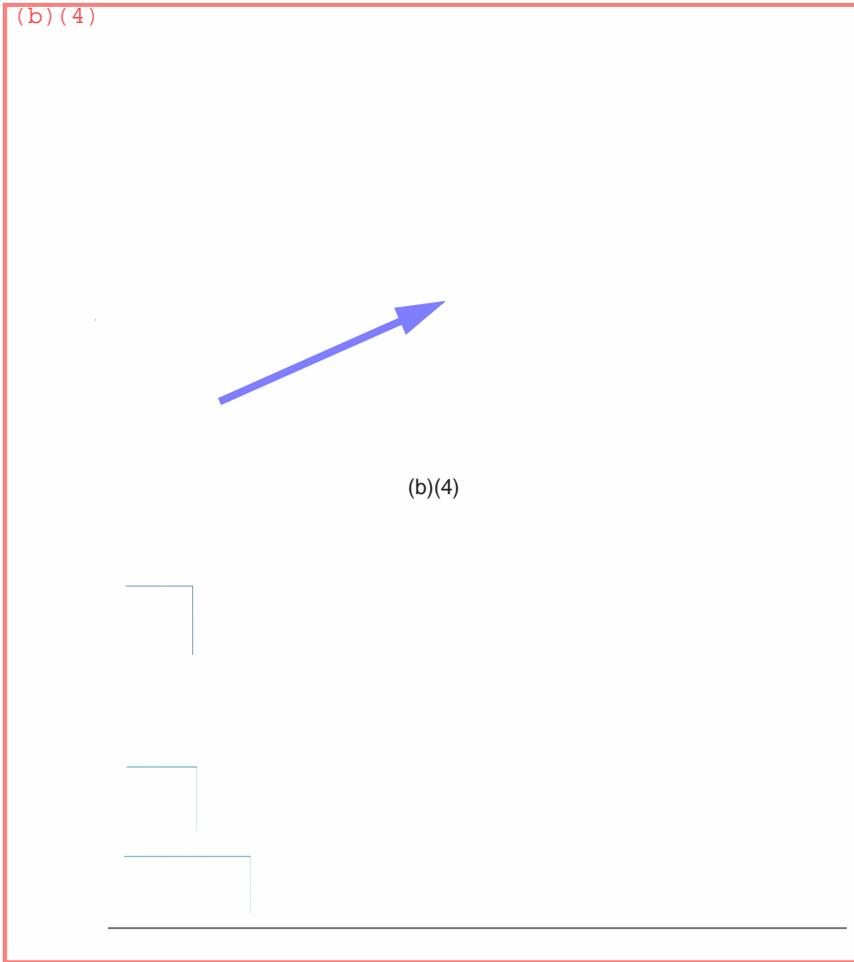
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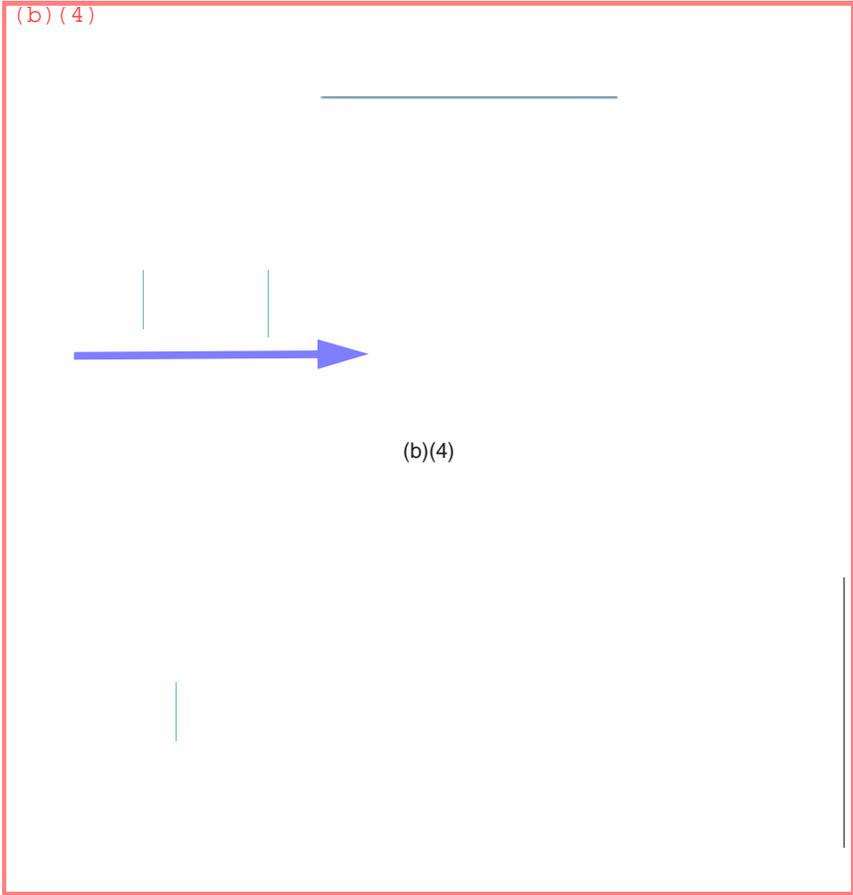




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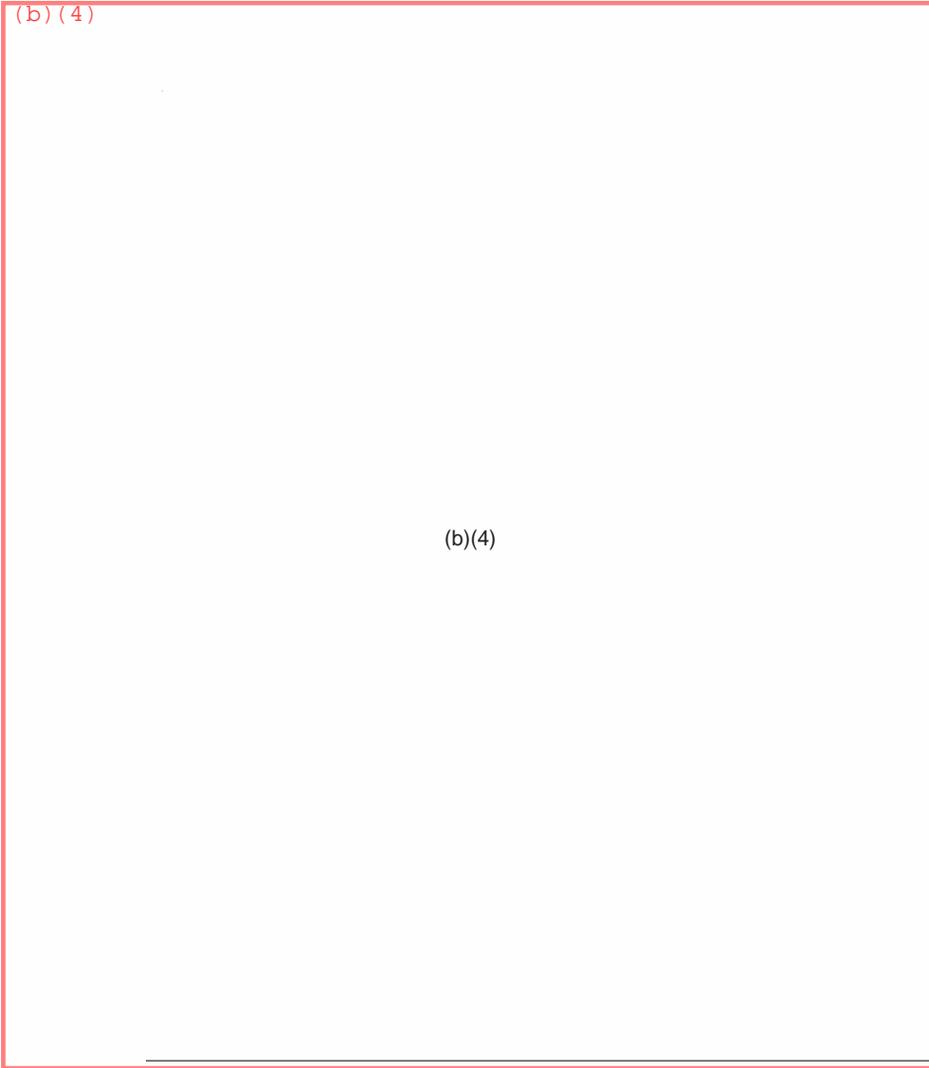
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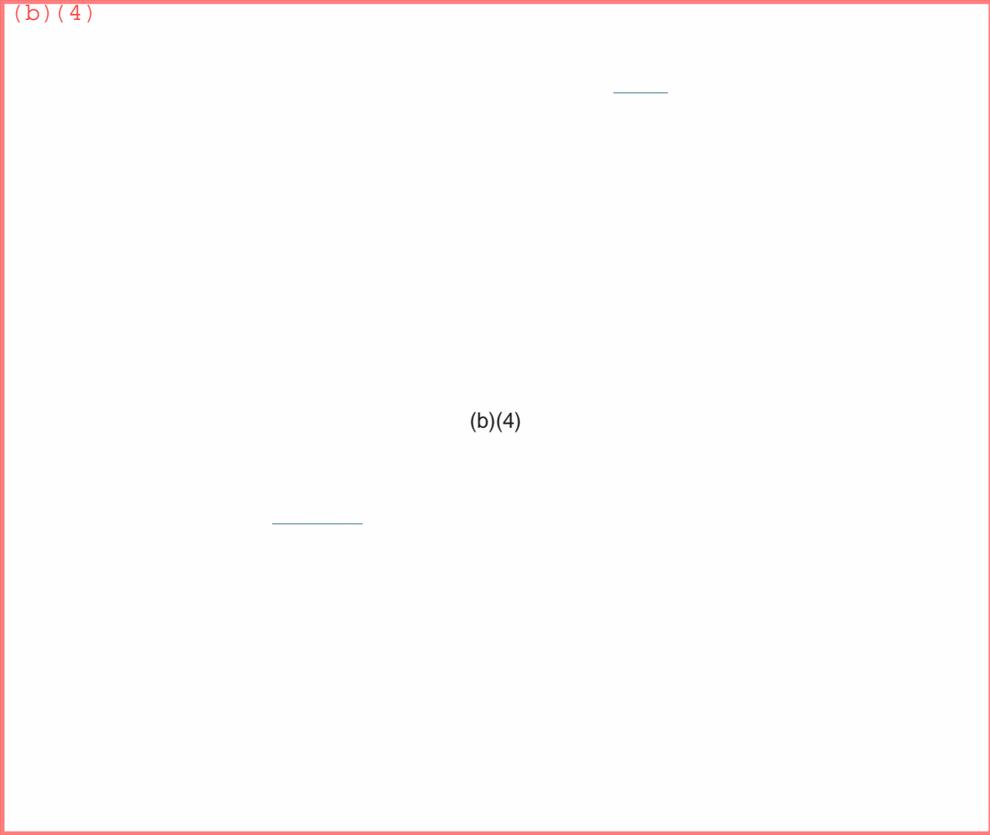




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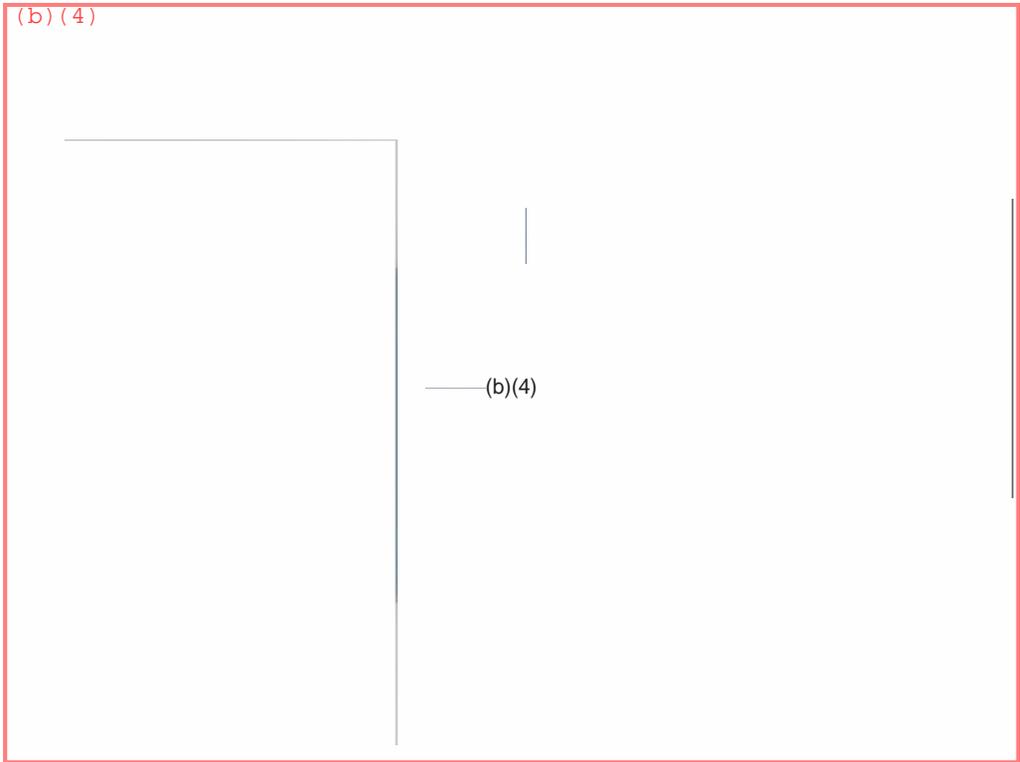
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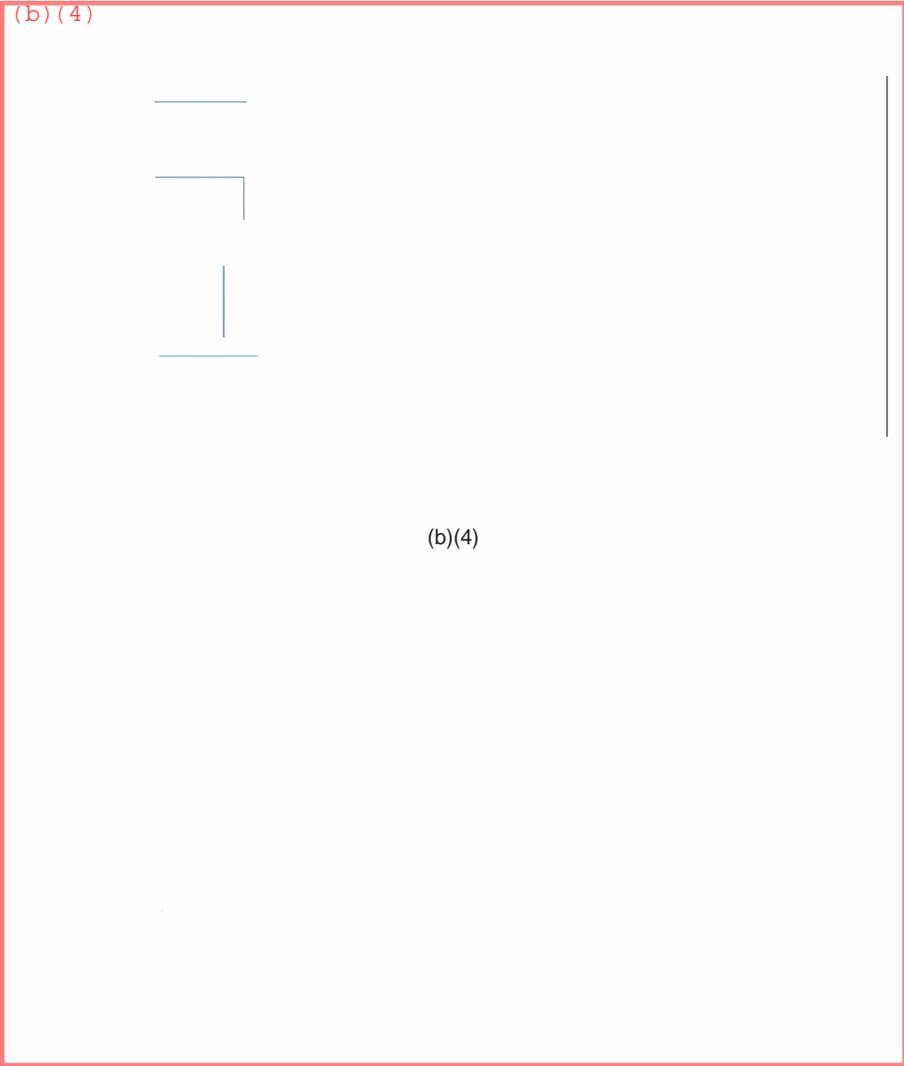




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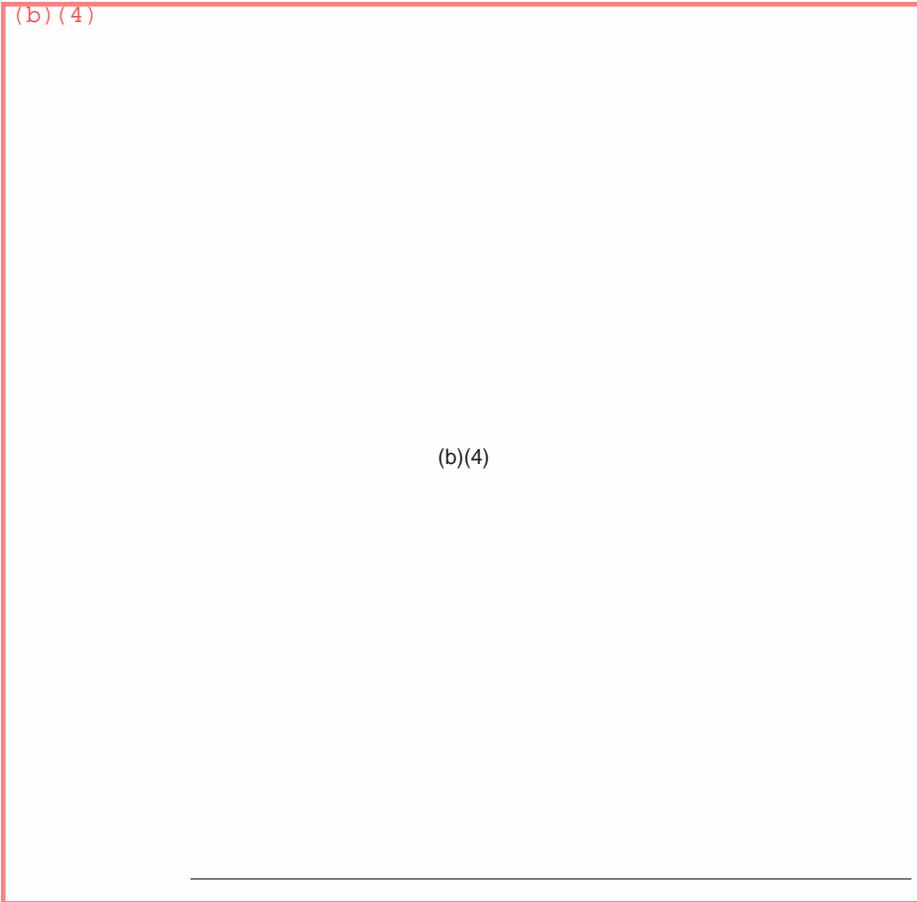
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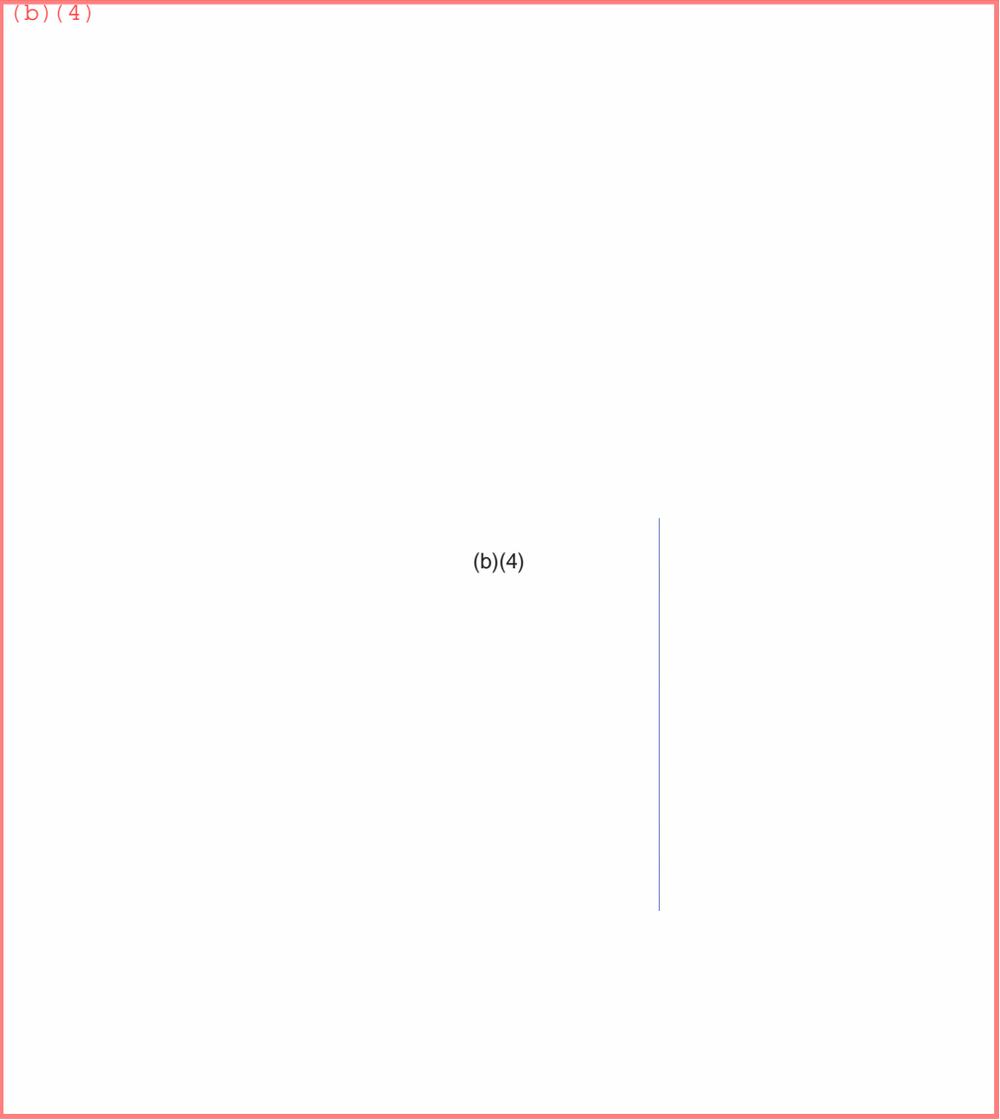




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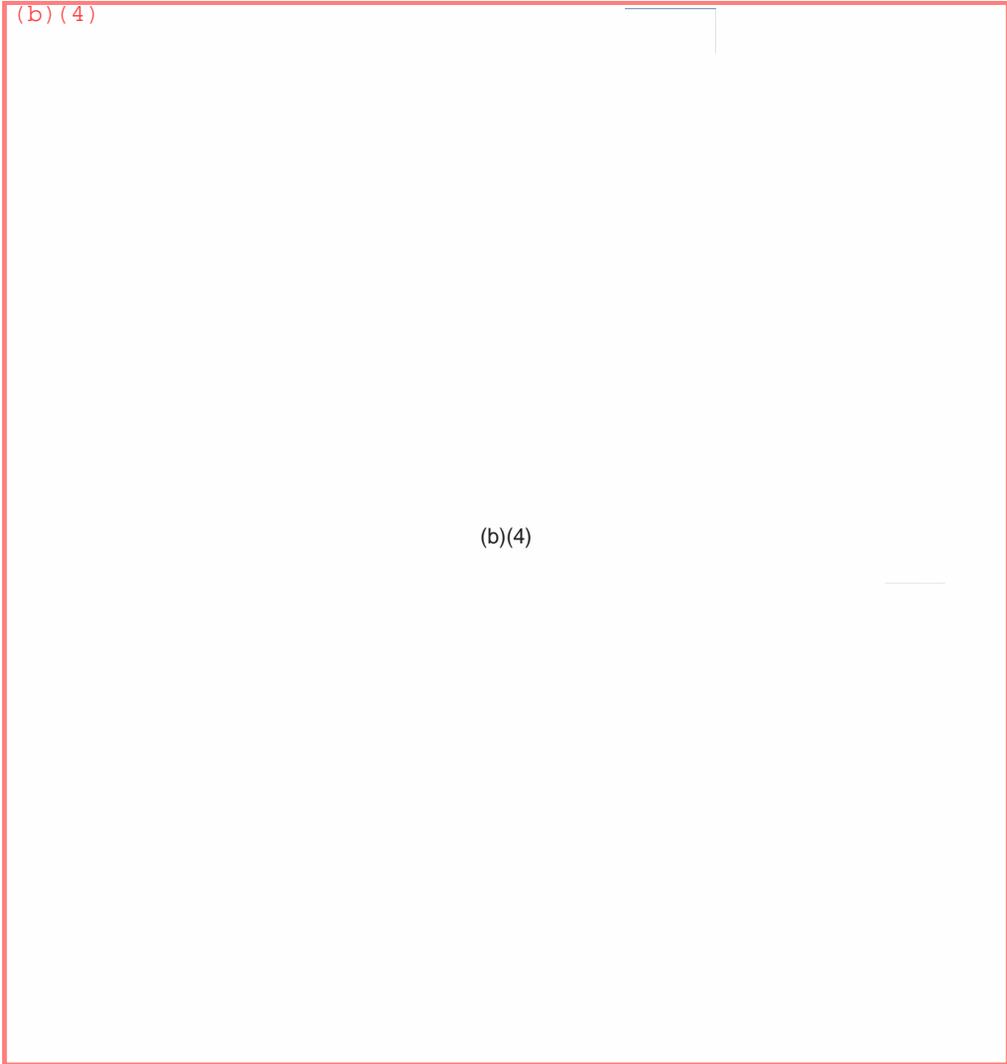
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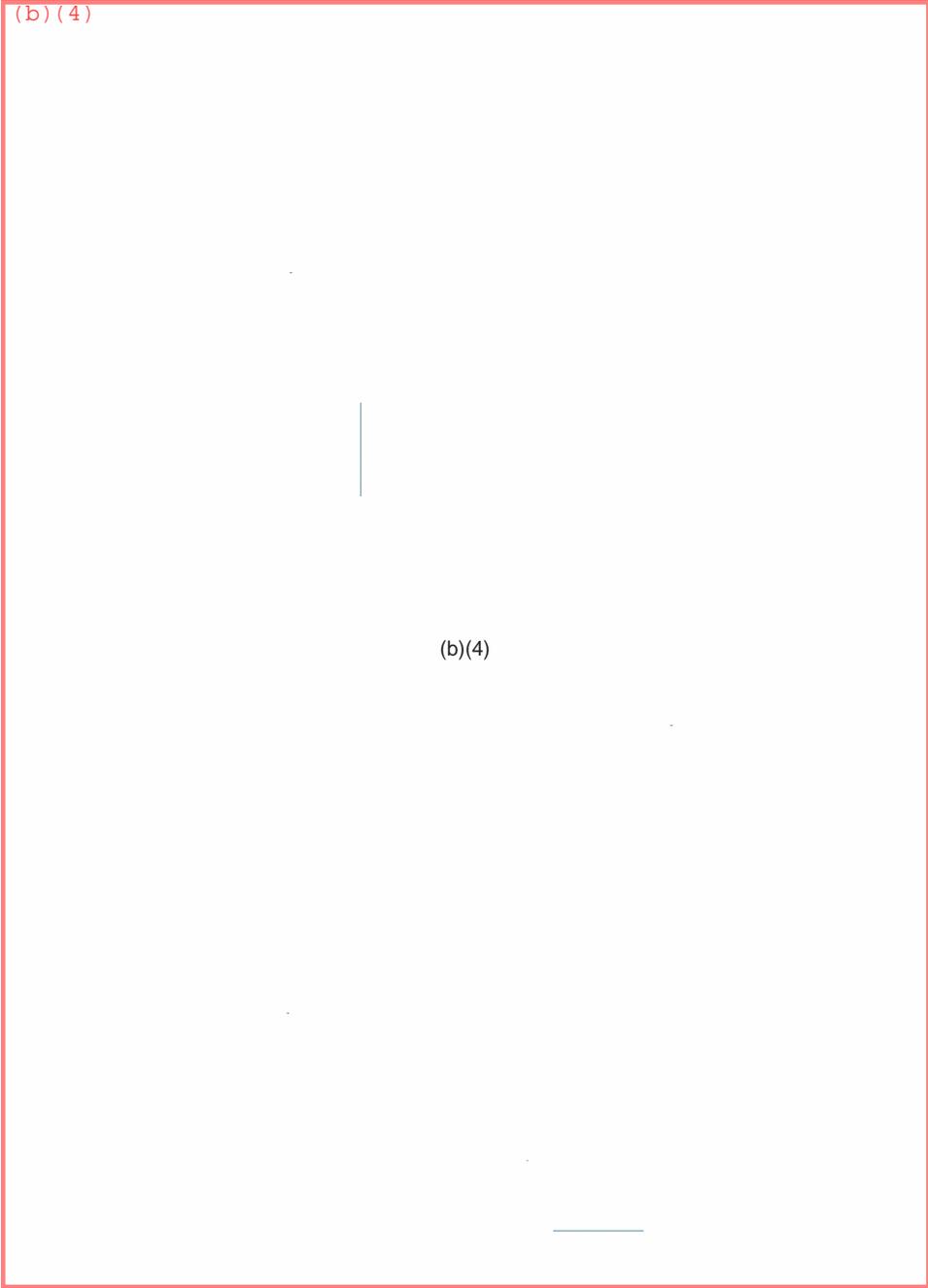




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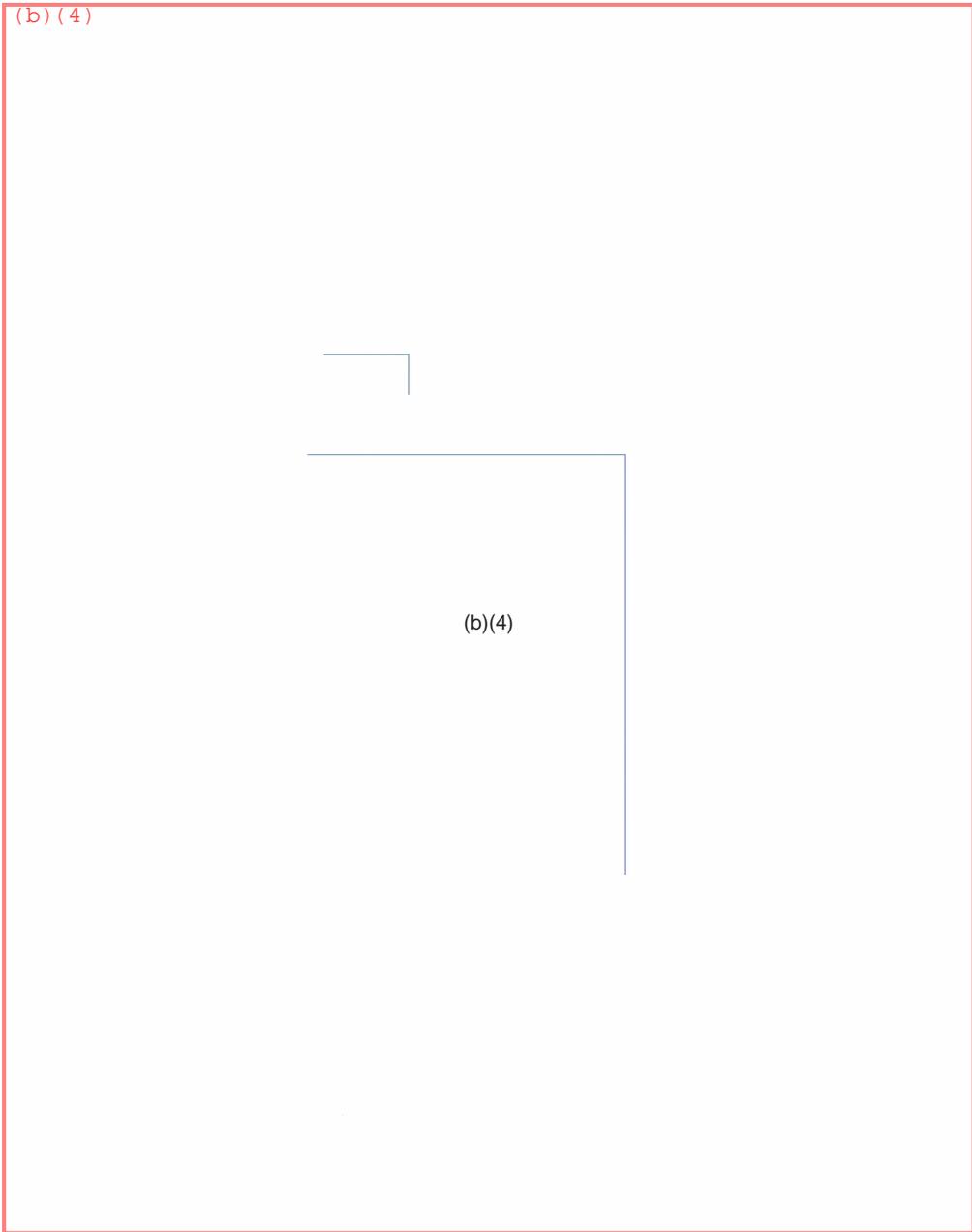
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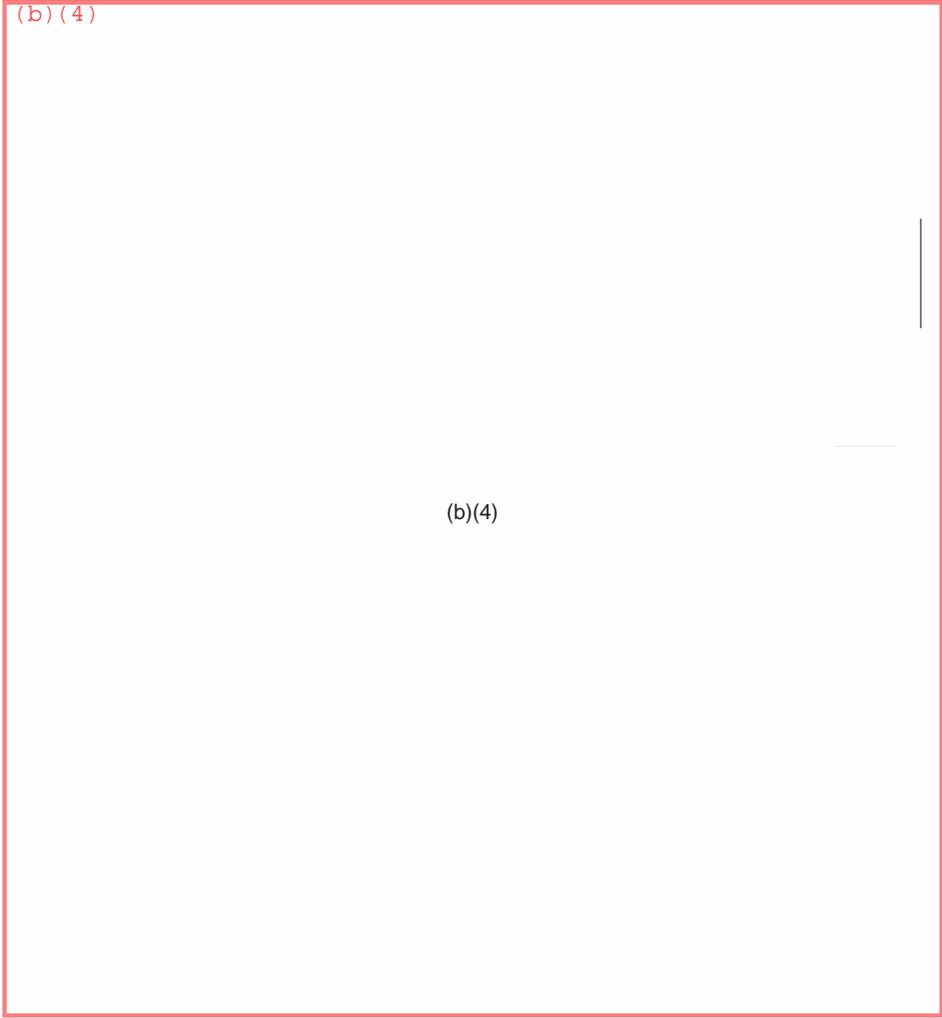




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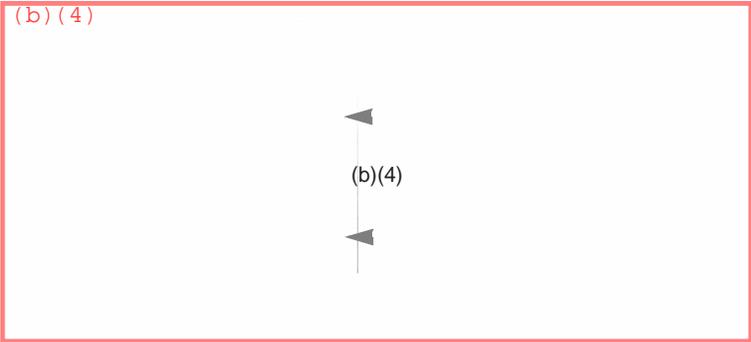
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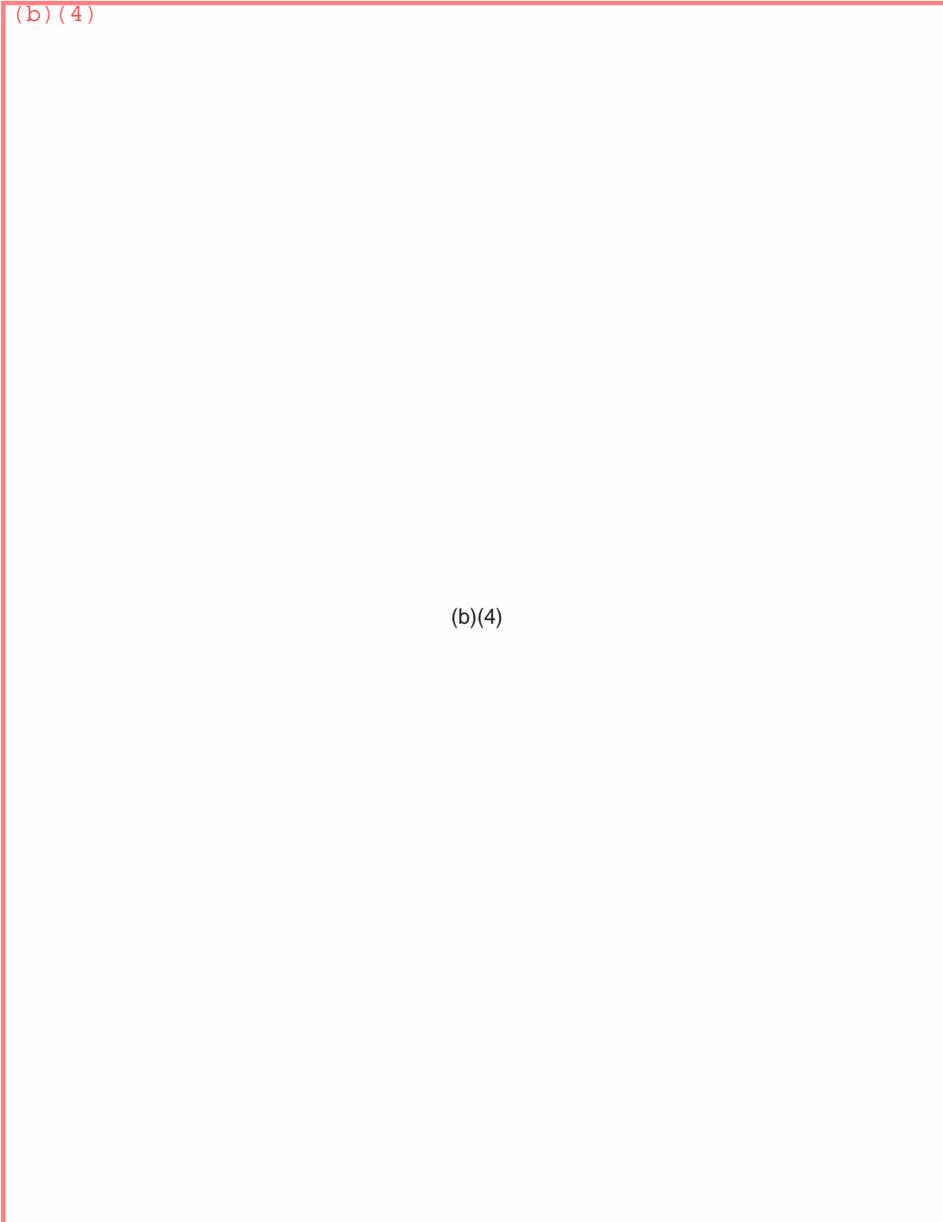


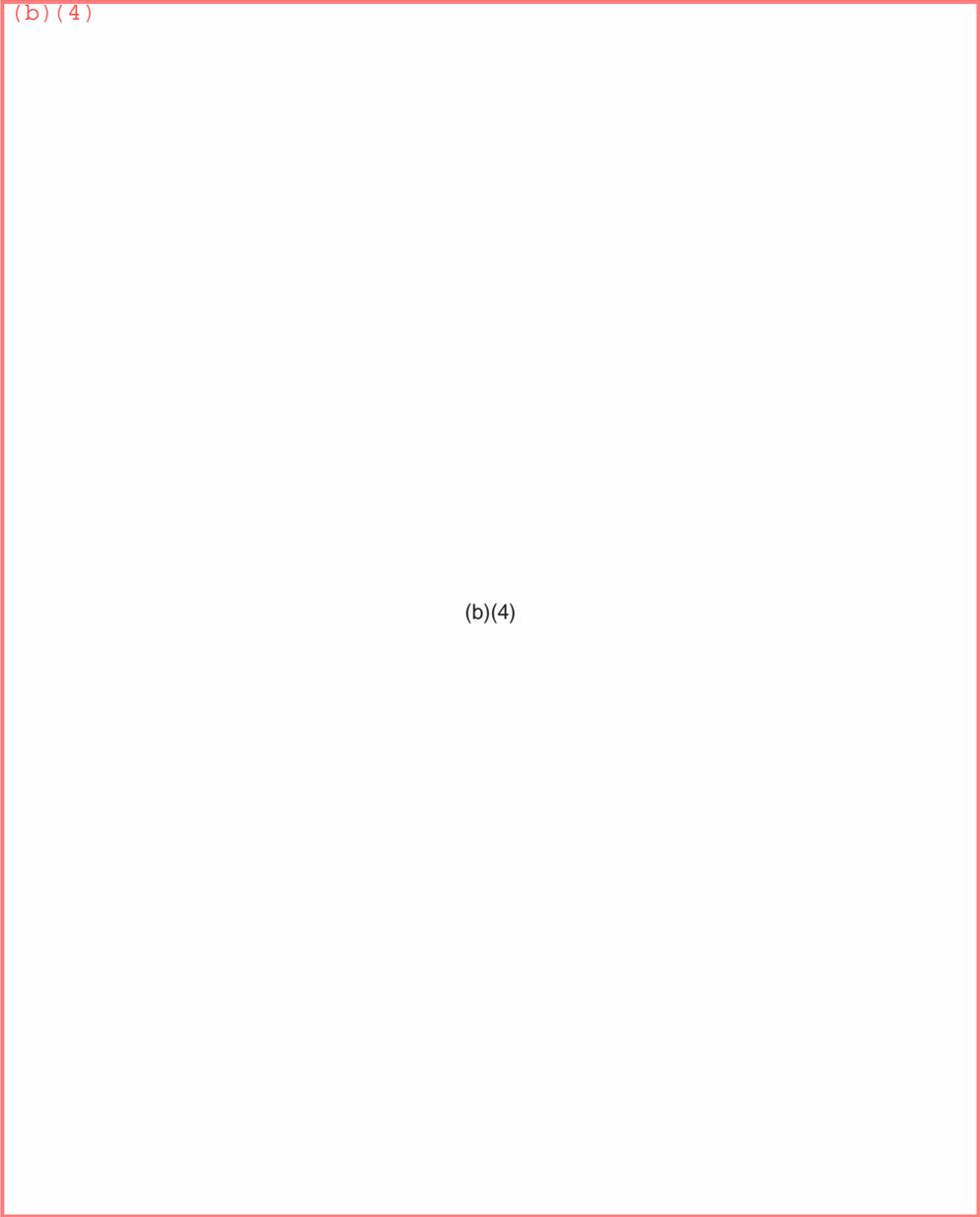
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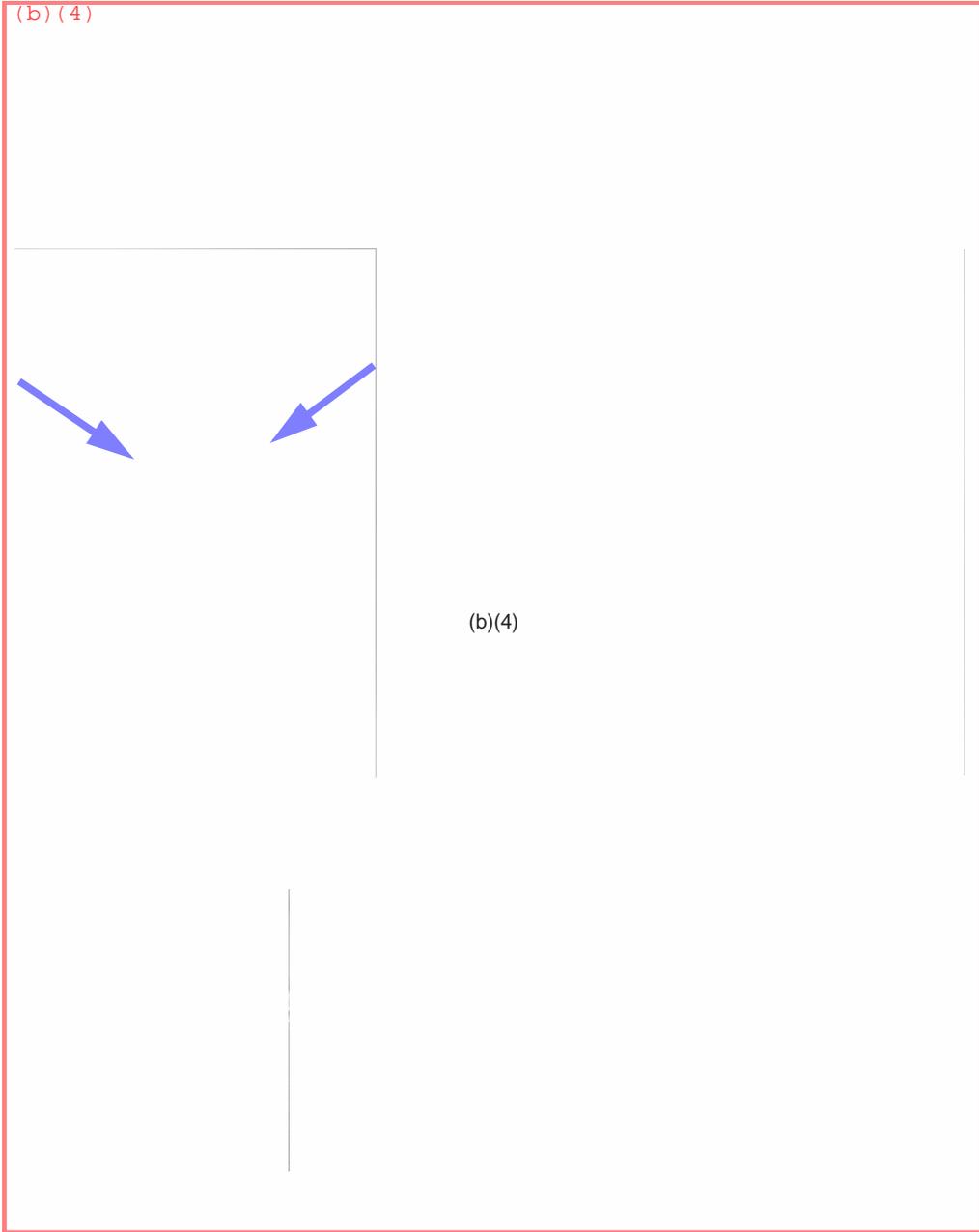
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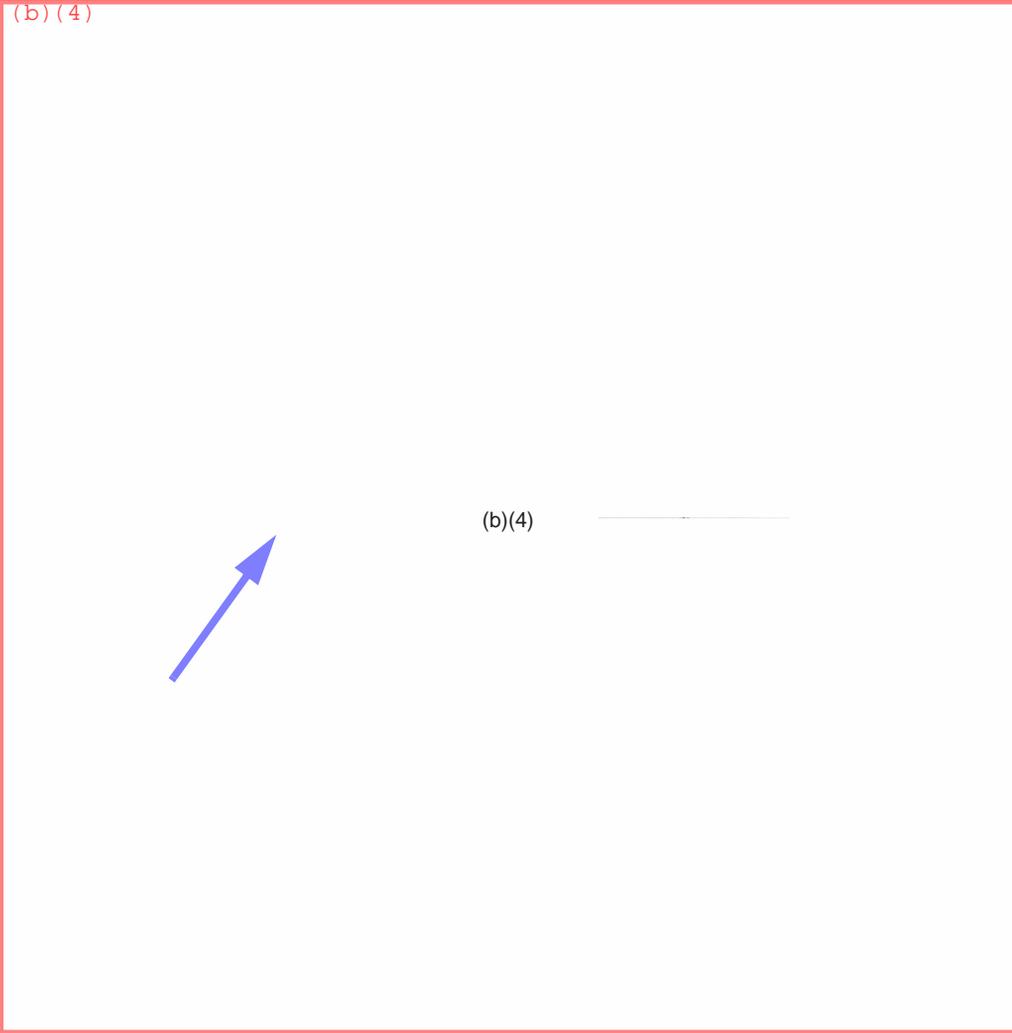
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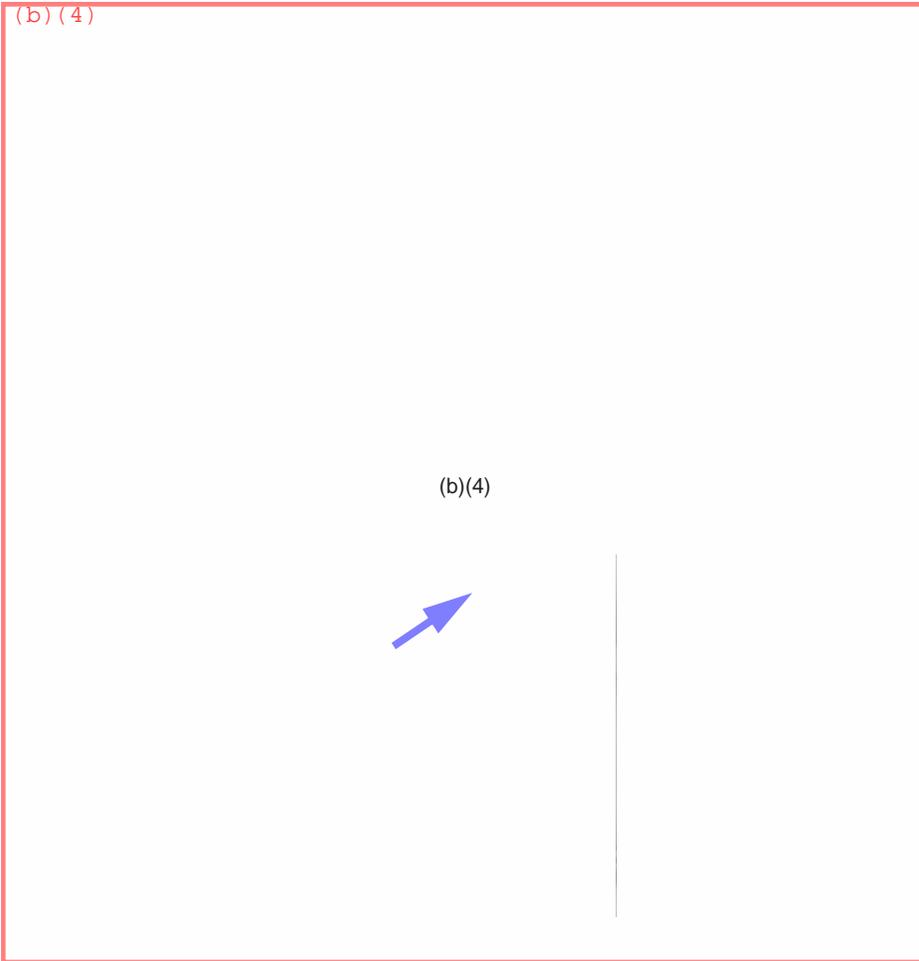
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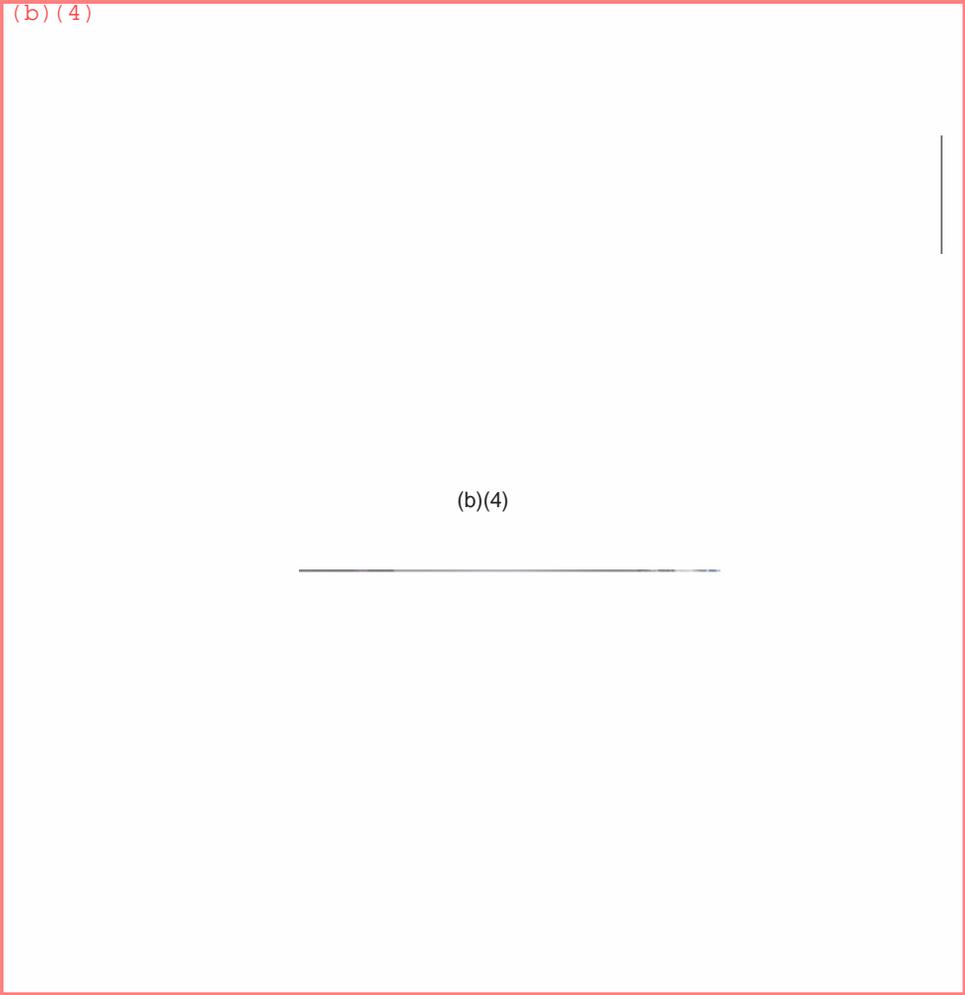




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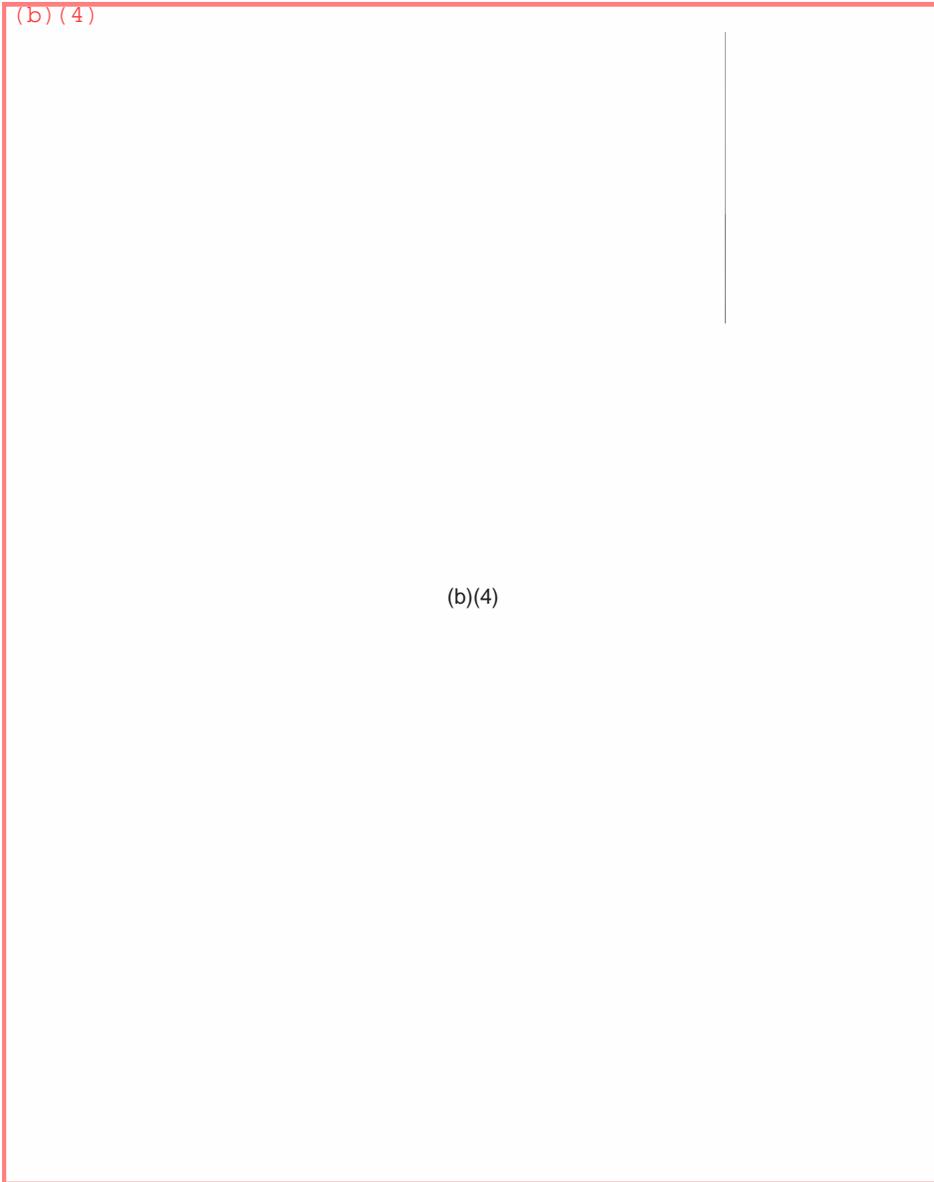
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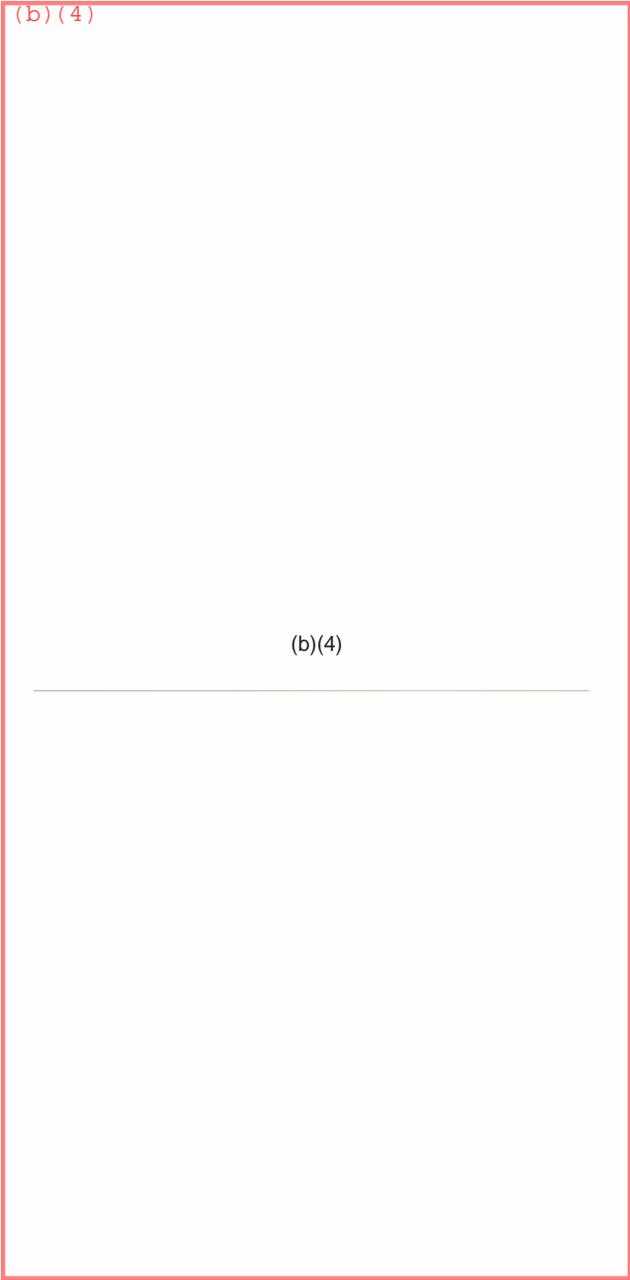




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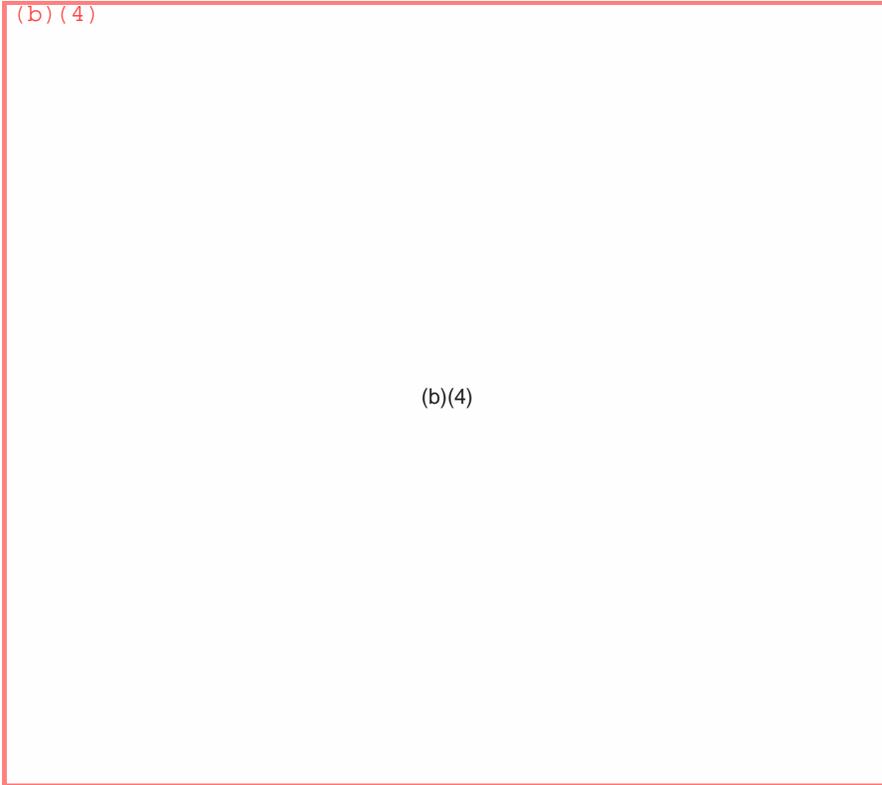
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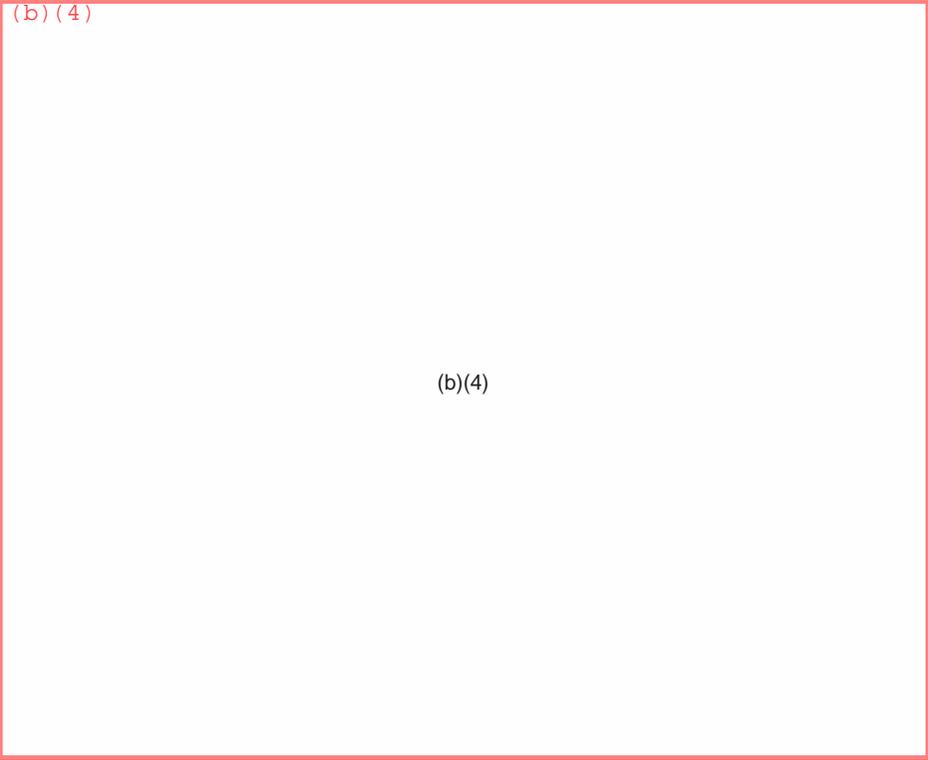




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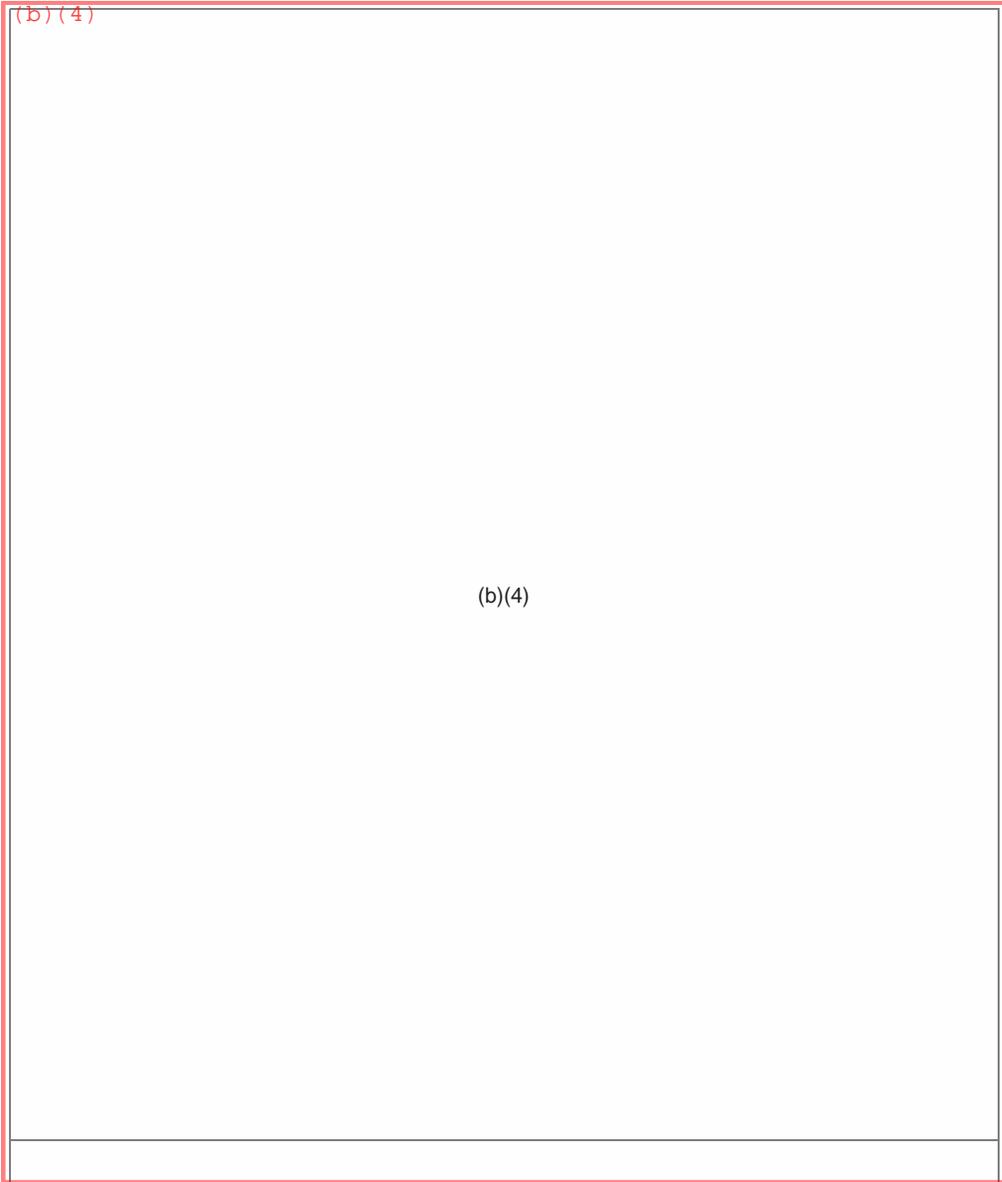
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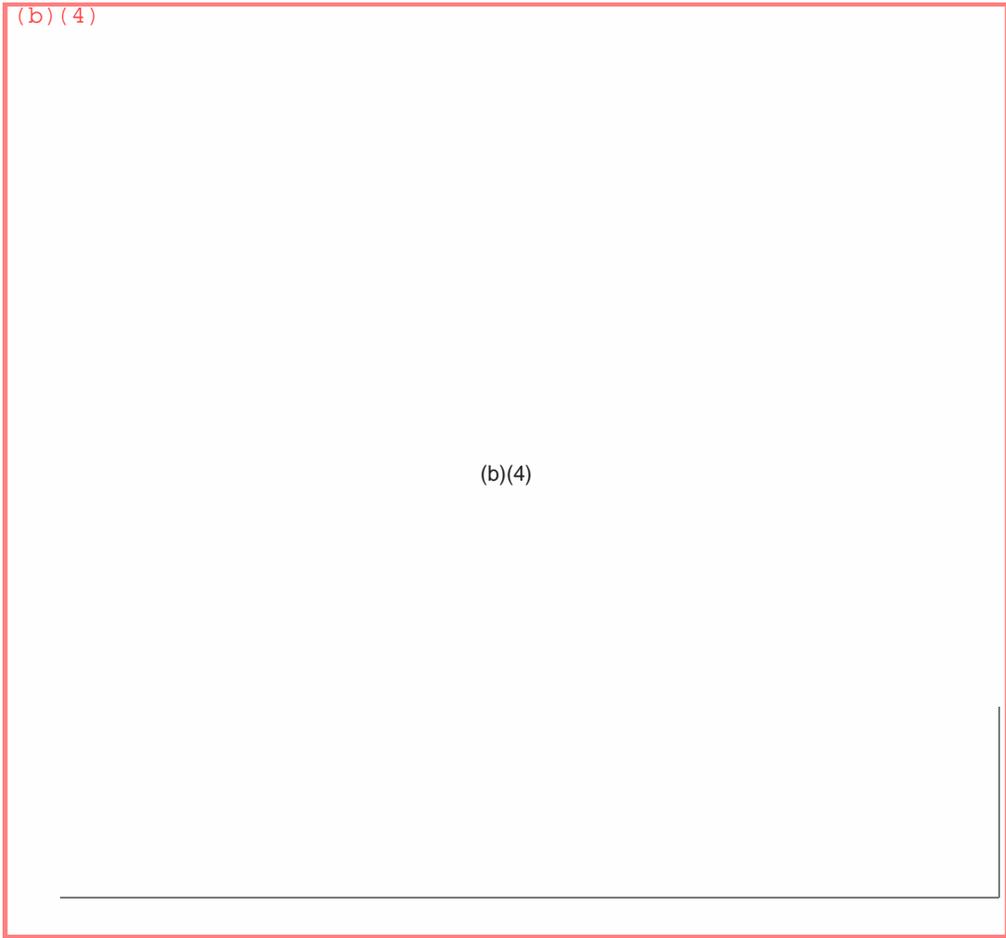
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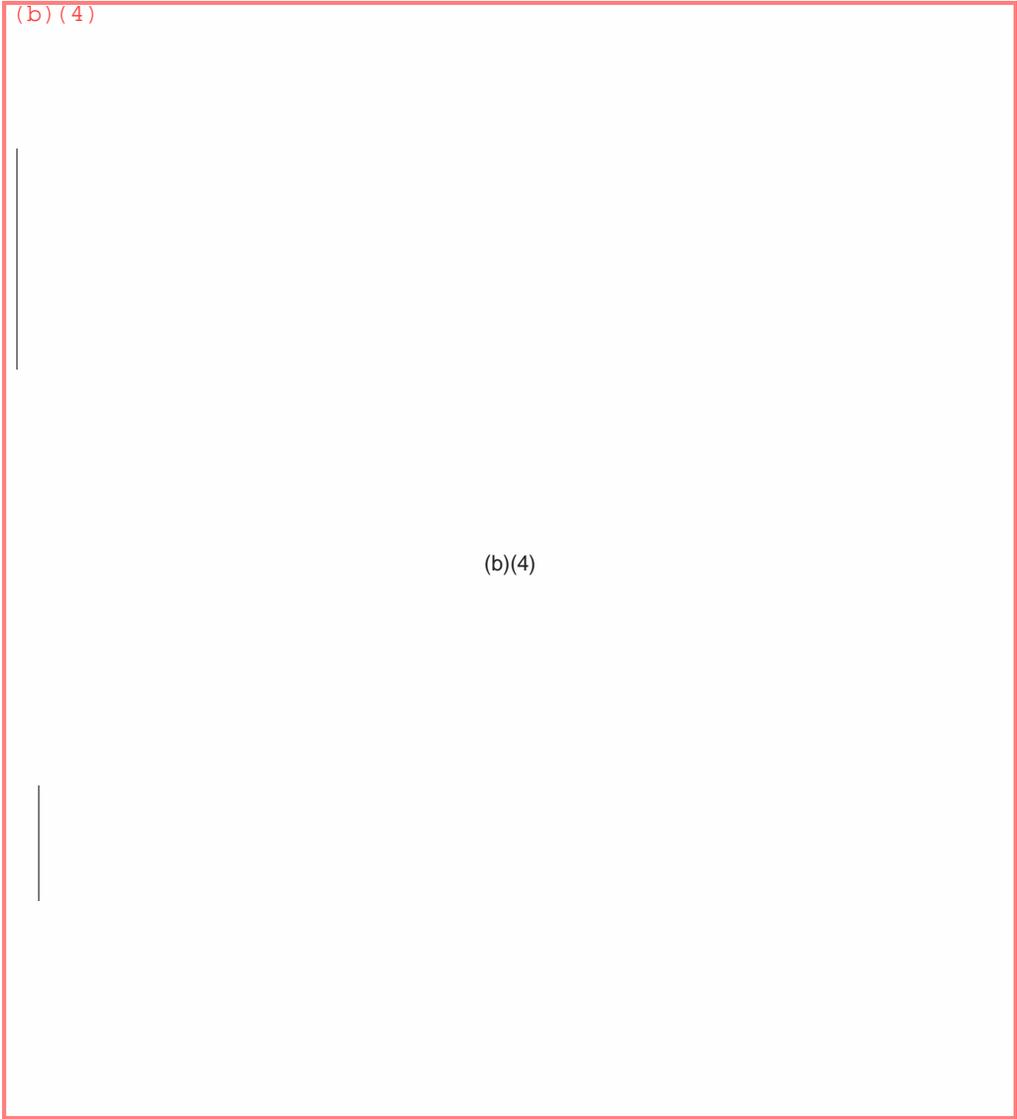
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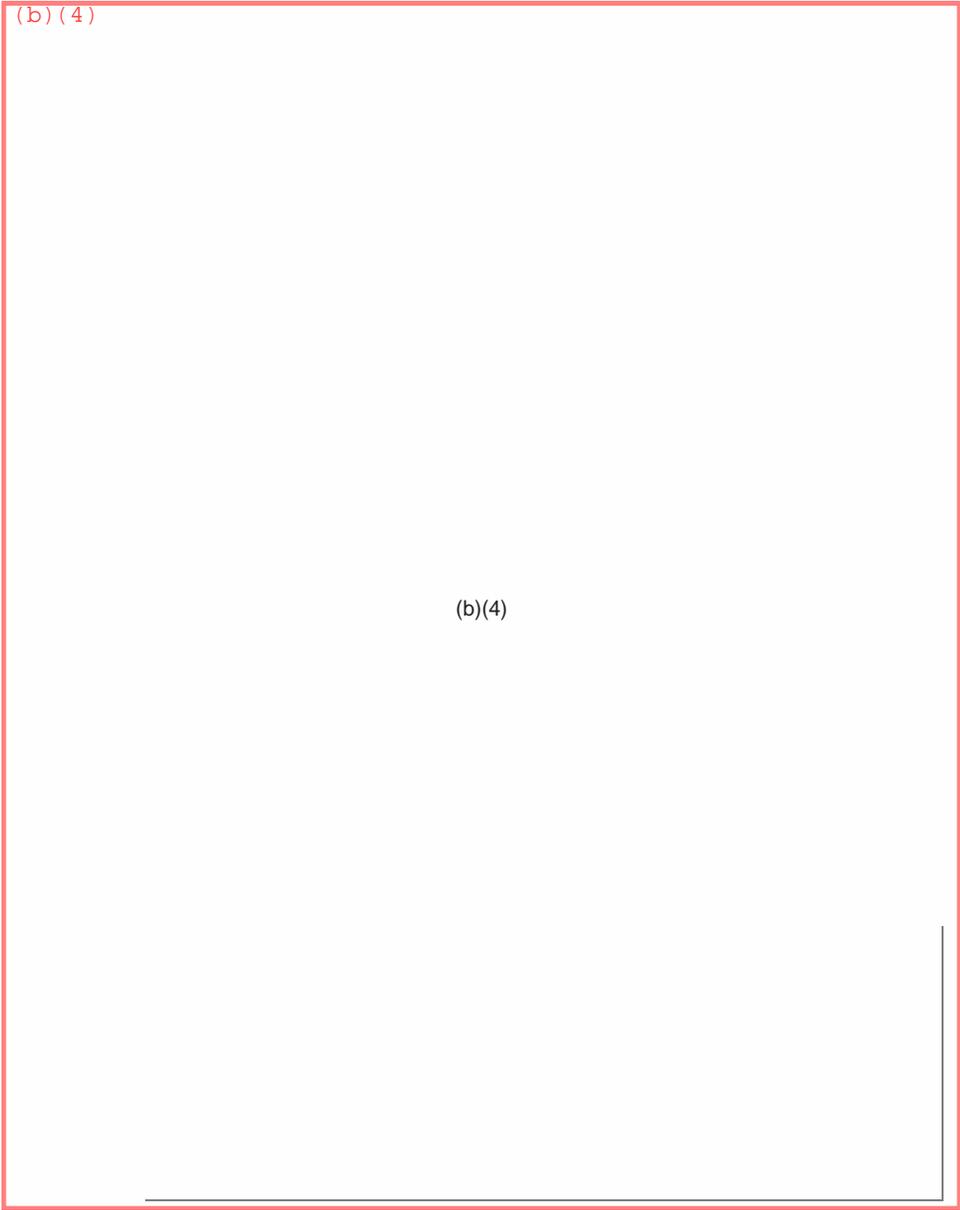
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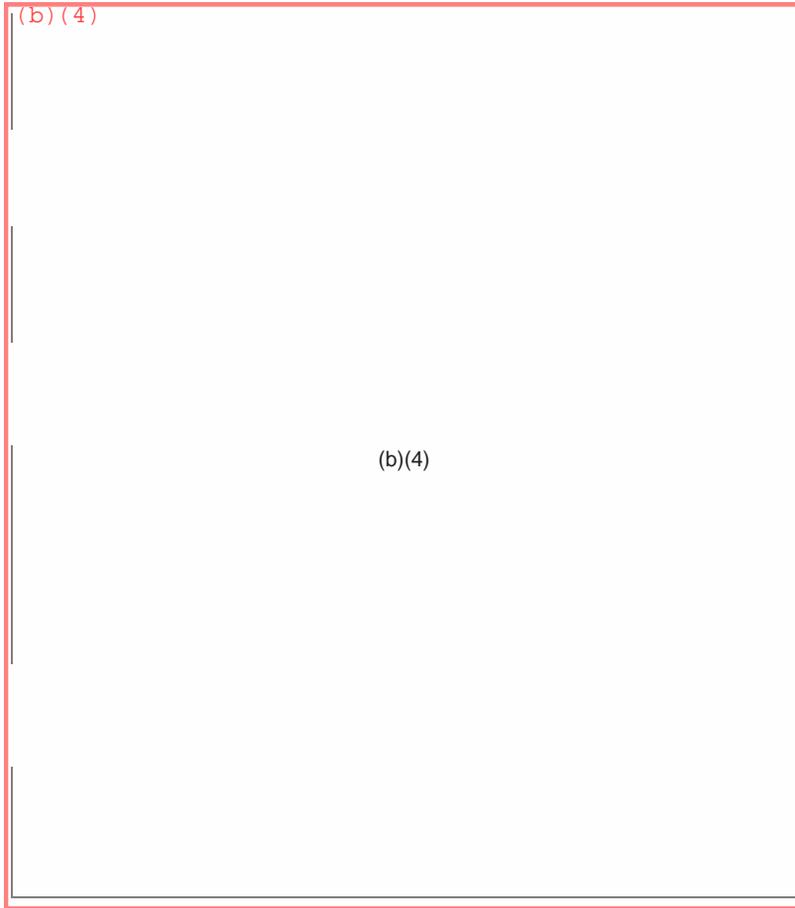
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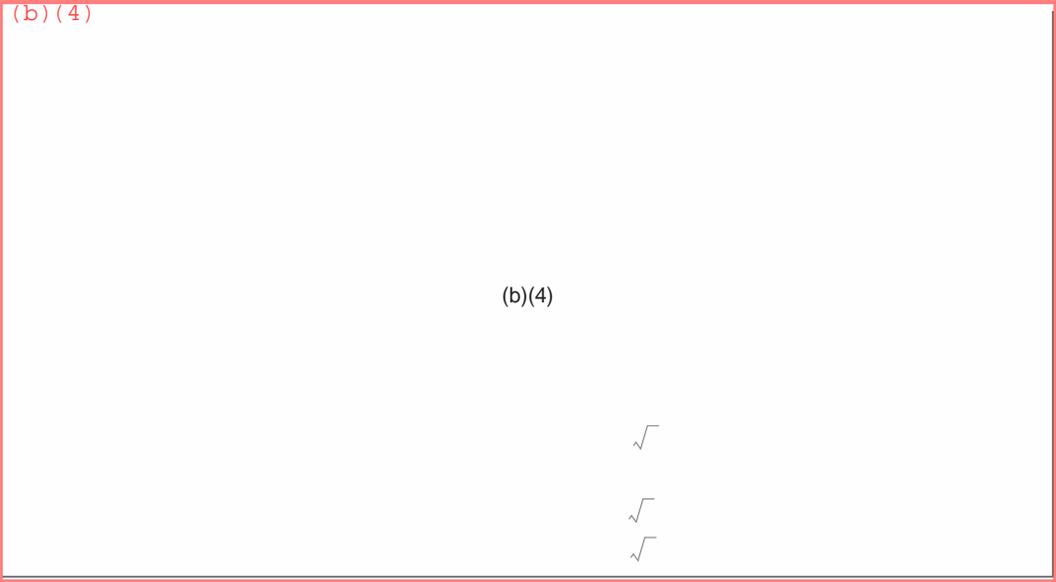
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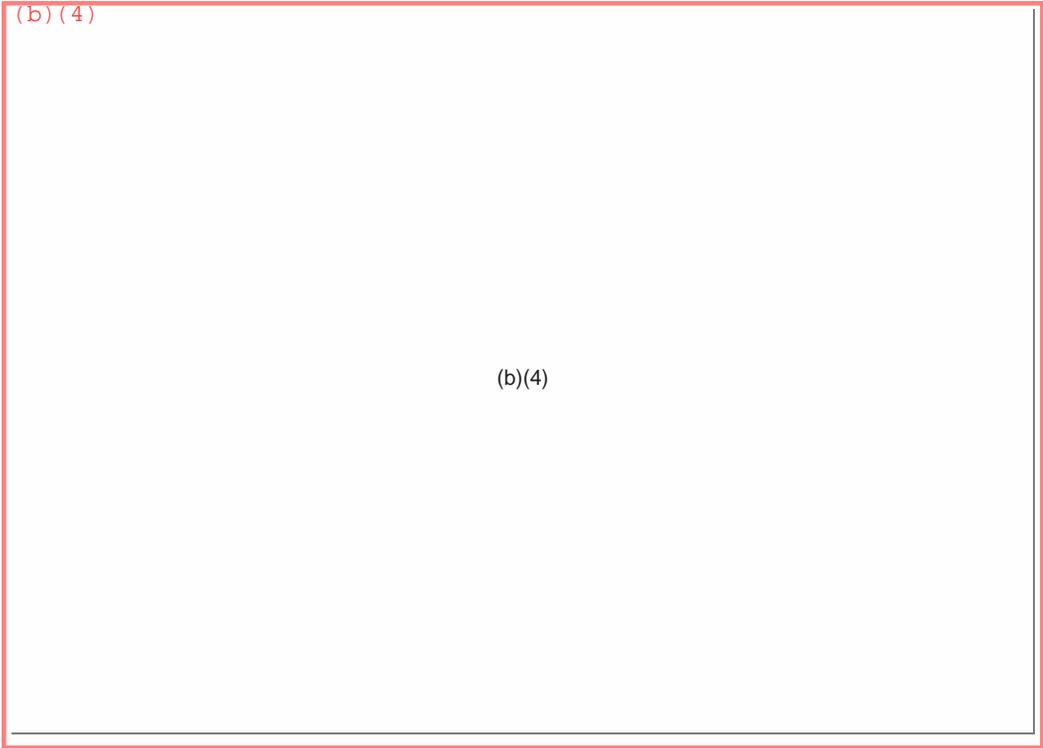
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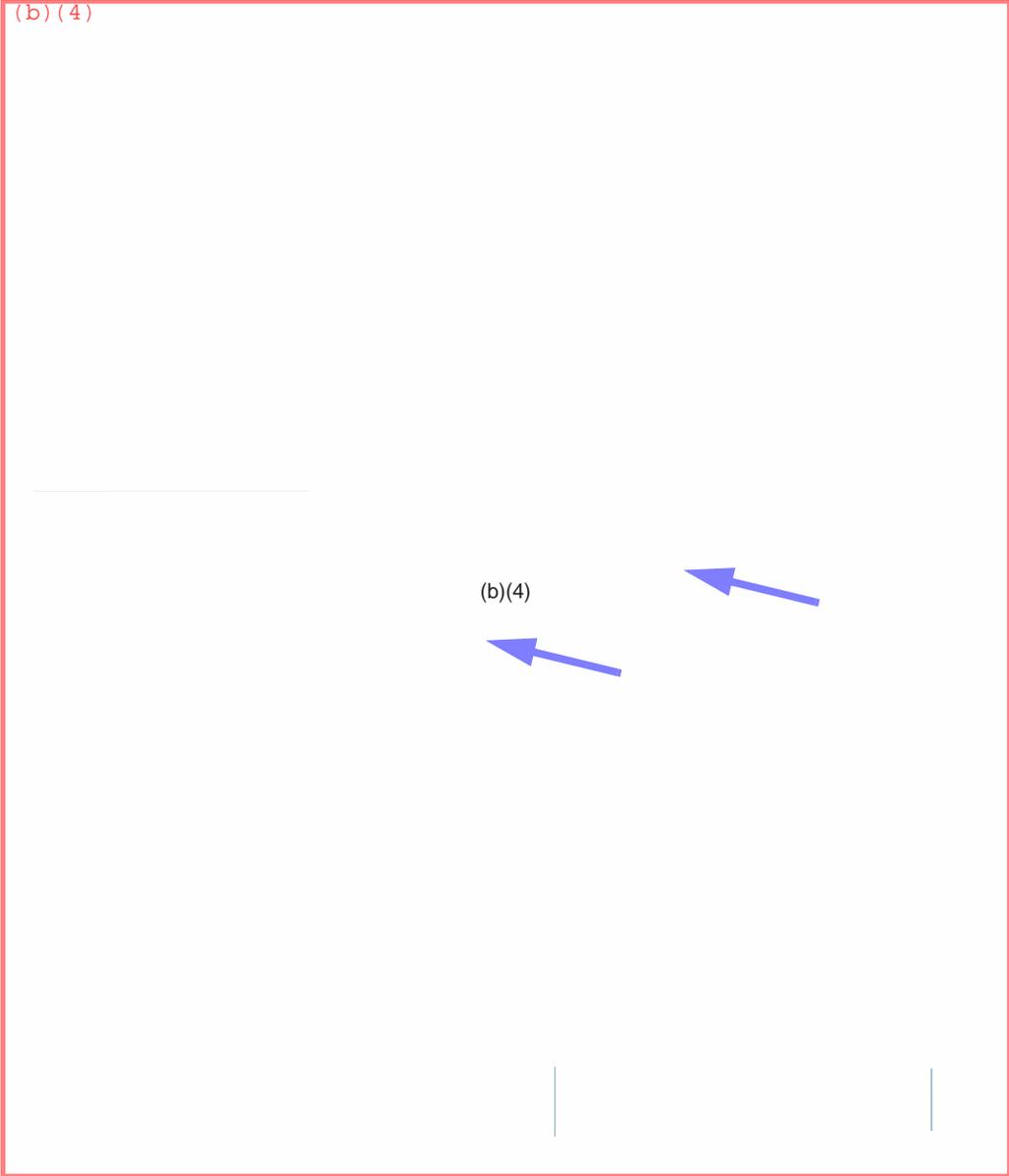
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Attachment 12-7: Zeltiq AcuCool Belt Sleeve Directions for Use



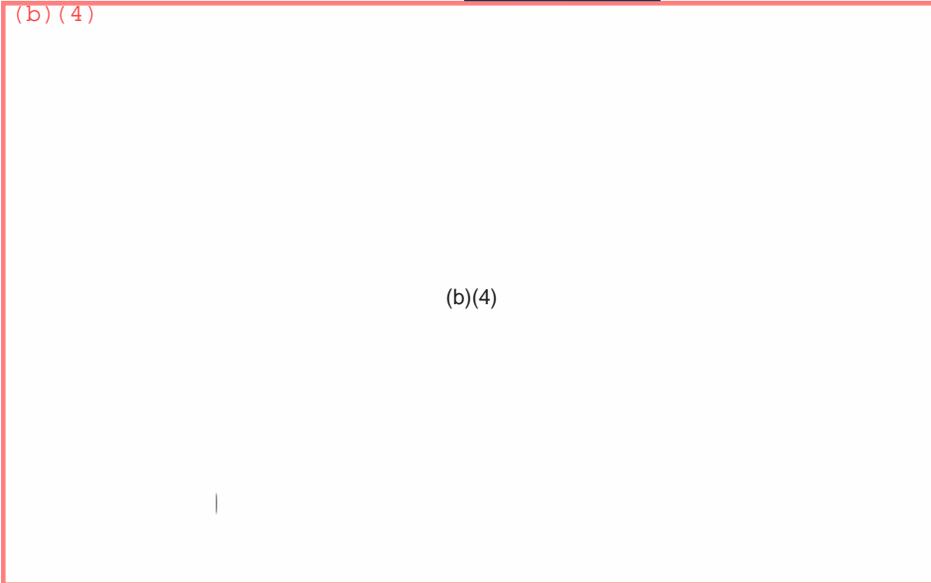
AcuCool Belt Sleeve Directions for Use

(b) (4)



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Refer to your contract.

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The products described in this document may be covered by one or more of the following U.S. Patents: 7,367,341, 6,032,075, and D568,258. Other patents and patent applications pending worldwide.

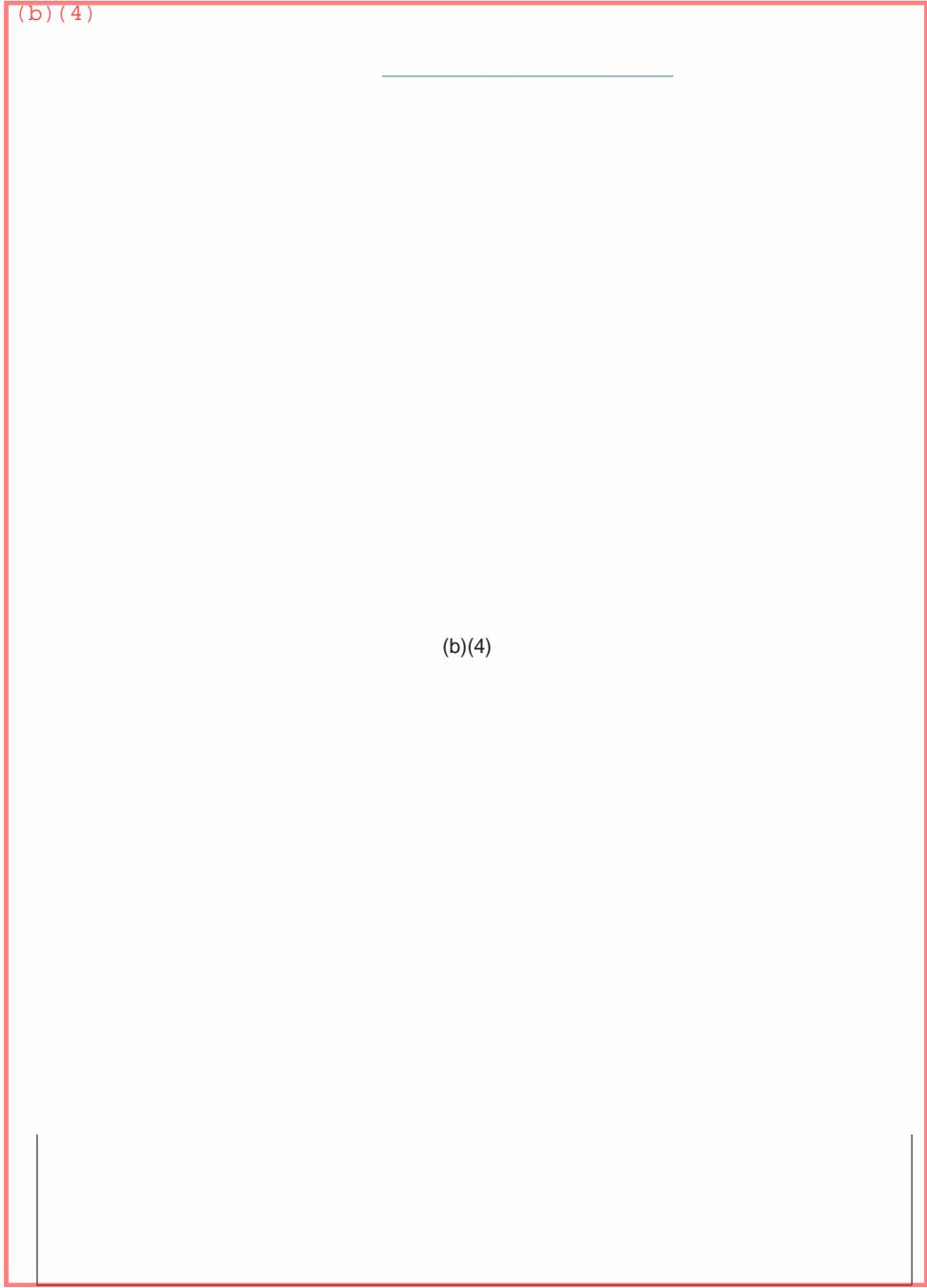
	<p>Zeltiq Aesthetics, Inc. 4698 Willow Road Pleasanton, CA 94588 U.S.A. (925) 474-2500 www.zeltiq.com</p>		<p>Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands Tel: (+31) 70 345 8570 Fax: (+31) 70 346 7299</p>
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Attachment 12-8: (b) (4) (b)(4)

(b)(4)

(b)(4)





Attachment 12-9: (b) (4) (b)(4)

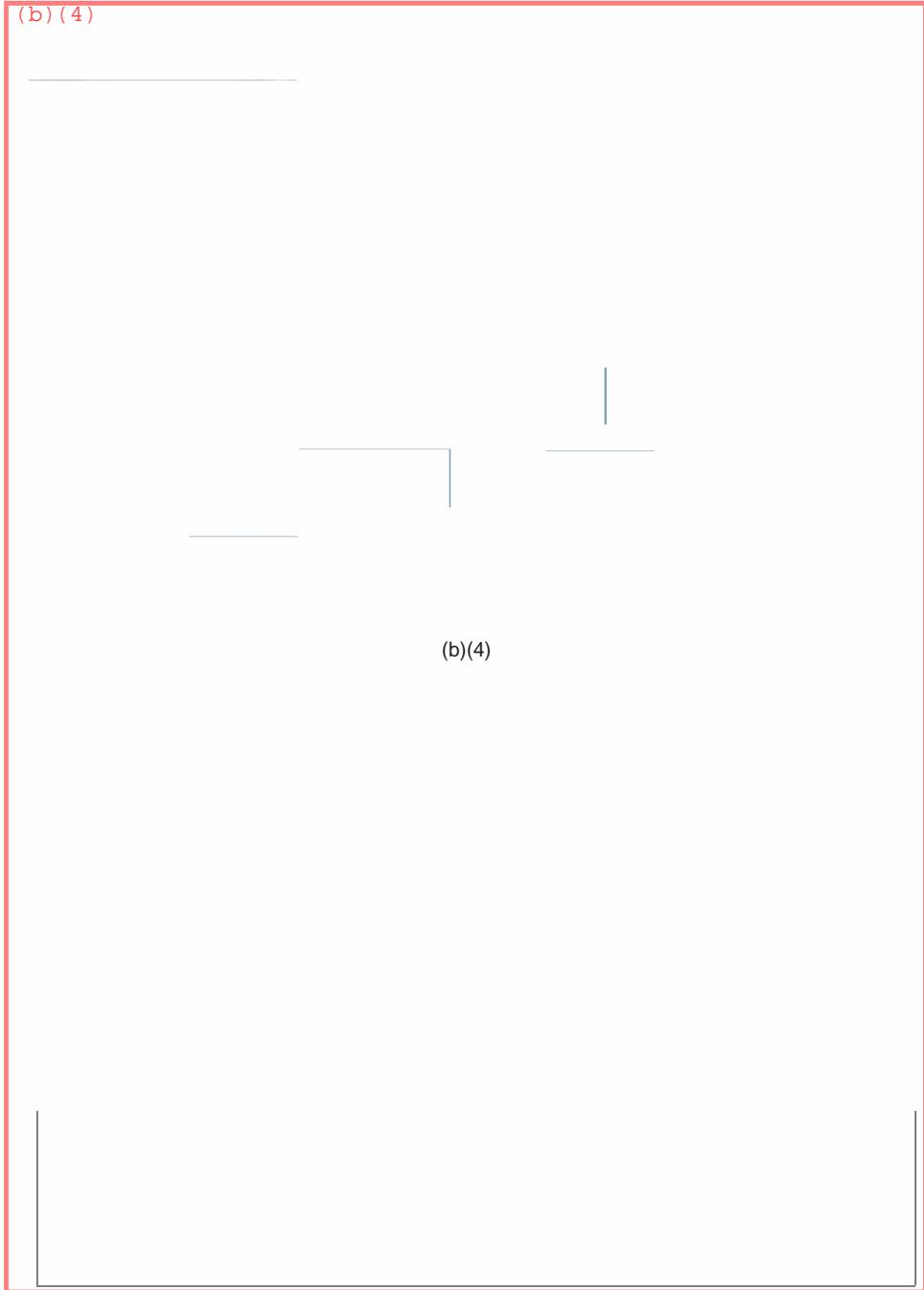


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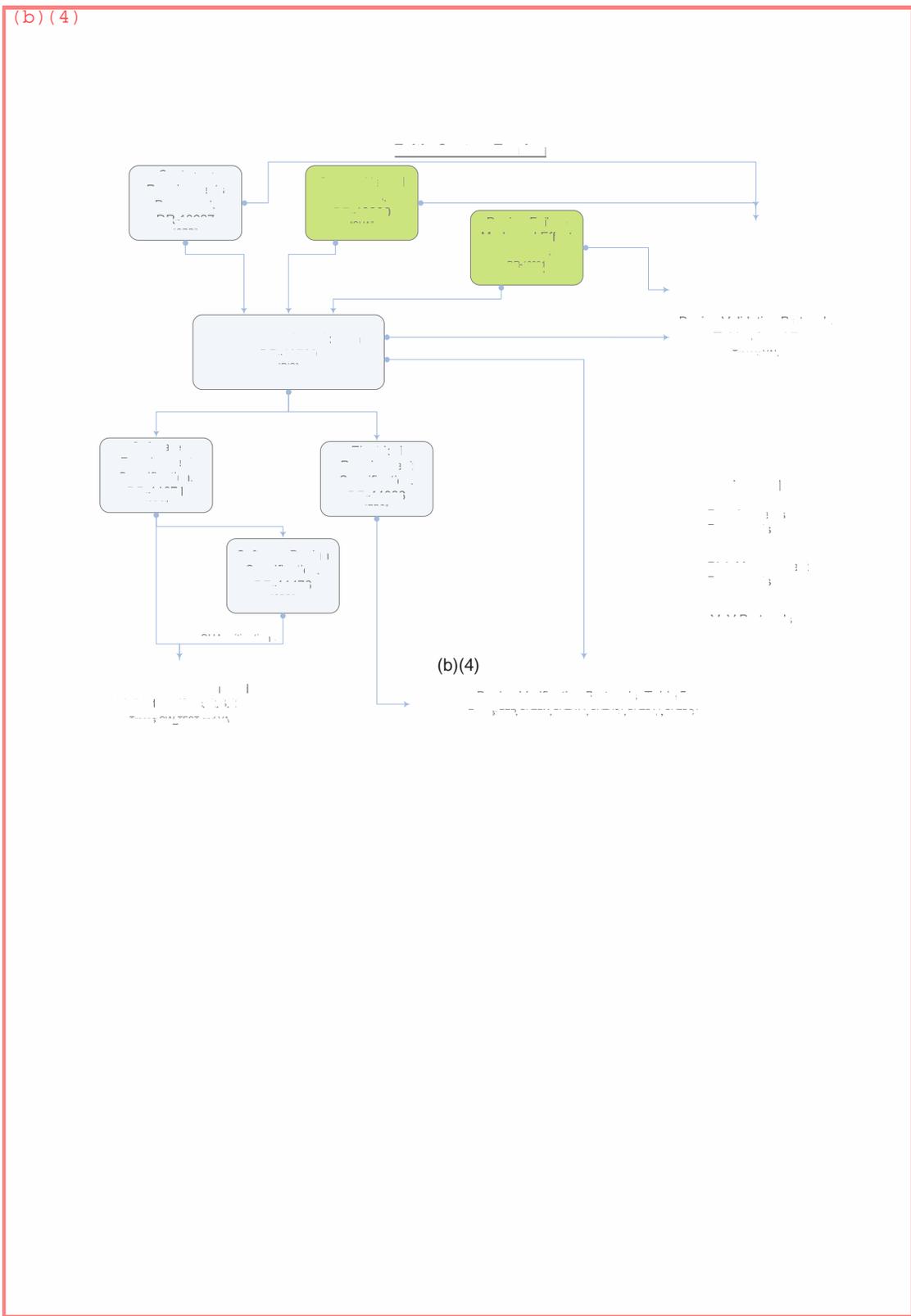
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(b)(4)



SECTION 13. SUMMARY OF DESIGN CONTROL ACTIVITIES



SECTION 13. SUMMARY OF DESIGN CONTROL ACTIVITIES

Table 6: Risk Control Measures Resulting From Risk Analysis along with Verification and Validation Activities and Results		
	Test Method	Result
(b) (4) * * * (b)(4) * *	Electrical testing	Pass
	Software verification	Pass
	Electrical testing and Software verification	Pass
	Software verification	Pass
	Electrical testing and Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Inspection of material datasheets	Pass
	Inspection of DFU	Pass
	Inspection of DFU	Pass
	Inspection of DFU	Pass

SECTION 13. SUMMARY OF DESIGN CONTROL ACTIVITIES

Table 6: Risk Control Measures Resulting From Risk Analysis along with Verification and Validation Activities and Results		
	Test Method	Result
(b)(4) * * * * * * *	Inspection and Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Software verification	Pass
	Inspection of DFU	Pass
	Inspection of DFU	Pass

SECTION 13. SUMMARY OF DESIGN CONTROL ACTIVITIES

Attachment 13-1: Declaration of Conformity

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Declaration # ZEL02
Manufacturer's Name: Zeltiq Aesthetics, Inc.
Business Address: 4698 Willow Road
 Pleasanton, CA 94588
 USA
Object of the declaration: Medical Devices listed in Schedule A

I attest that:

1. As required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and
2. The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

Authorized Signatory:

Donald V. Johnson Date
Vice-President of Operations

SECTION 13. SUMMARY OF DESIGN CONTROL ACTIVITIES

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Schedule A

Accessories for use with Zeltiq System (non-sterile), including:

Non-Sterile, Reusable

Part Name	Catalog Number
Zeltiq Breeze Control Unit - 110 VAC	BRZ-CG1-CTU-110
Zeltiq Breeze Control Unit - 220 VAC	BRZ-CG1-CTU-220
Zeltiq Breeze Applicator - Vacuum - 2 Panel	BRZ-CG1-APP-V02
Zeltiq Breeze Applicator - Belt - 3 Panel	BRZ-CG1-APP-B03
Zeltiq Gel 60ml bottles	BRZ-SP1-GEL-060

Non-Sterile, Single Use

Part Name	Catalog Number
Zeltiq AcuCool Vacuum Sleeve - 2 Panel	BRZ-SP1-SV2-002
Zeltiq AcuCool Belt Sleeve - 3 Panel	BRZ-SP1-SB3-002
Zeltiq Gelpads - 9 inch length	BRZ-SP1-GPD-009

14. STERILIZATION & SHELF LIFE

There are no changes from the Zeltiq CLN1 Dermal Cooling System: the Zeltiq System, including the applicators and disposable sleeves, are not sold sterile.

The shelf life for the Zeltiq AcuCool sleeves and Zeltiq Gelpads are 6 months.



COVER SHEET MEMORANDUM

From: Reviewer-Name Long Chen
 Subject: 510(k) Number K 0900 94 / 52
 To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist. http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202007.doc)
 - Hold (Additional Information or Telephone Hold).
 - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/CO-MBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days - < 2 years old)			X
Child (2 years - < 12 years old)			X
Adolescent (12 years - < 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB:		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC:		

Regulation Number: 21 CFR 878.4810 Class*: II Product Code: GEX

Additional Product Codes: ILO, ISA (*If unclassified, see 510(k) Staff)

Review: [Signature] (Branch Chief) GSDB (Branch Code) 5/19/09 (Date)

Final Review: [Signature] (Division Director) [Signature] (Date)

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

TO: THE FILE

RE: DOCUMENT NUMBER **K090094/S2**

DATE: May 18, 2009

OFFICE: HFZ-410

FROM: Long Chen, Ph.D. Chemical Engineer

DIVISION: DGRND/GSDB

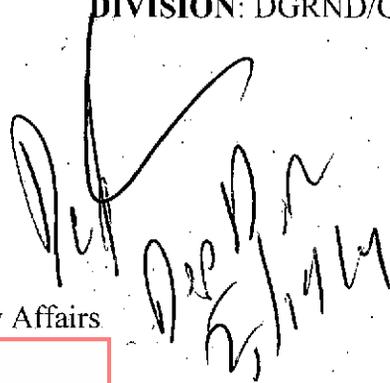
DEVICE NAME: Zeltiq System

COMPANY NAME: Zeltiq Aesthetics
Pleasanton, CA

CONTACT: Donald V Johnson
VP Operations, Regulatory, & Quality Affairs

(b)(4)

(b)(4)



Handwritten signature and date: 5/19/09

This 510(k) submission contains information/data on modifications made to the sponsor's own Class II devices. The following items are presented and acceptable:

1. NAME, 510(k) NUMBER AND PREDICATES:

The sponsor's previously cleared predicate device for this submission is:
Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118).

2. INDICATIONS FOR USE

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, and for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

This **INDICATION/INTENDED USE** of the modified device **HAS NOT CHANGED**.

The proposed Zeltiq System User Manual (Attachment 1, K090094/S2) is included. It is found to be adequate.

3. MODIFICATION(S) OF THE DEVICE

The Zeltiq System is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It consists of the following components: Zeltiq breeze control unit, Zeltiq breeze applicator (belt and vacuum styles are available), Zeltiq AcuCool sleeve (belt and vacuum styles are available), Zeltiq Gelpad, and Zeltiq Gel.

According to the sponsor, the modifications are in the following:

Zeltiq Breeze Control Unit (incl. software)

- Improved industrial design of unit
- Redesign umbilical support arm for improved ergonomics
- Separable upper and lower modules
- Increased size of touch screen display
- Integrated (all-in-one) interface between control unit and applicator
- (b) (4)
- (b)(4)
- Adjustable voltage power supply (to support future applicators)
- (b) (4) (b)(4)
- Updated software and enhanced graphical user interface
 - Improved control algorithm
 - Patient call functionality
 - Improved error handling

Zeltiq Breeze Applicator (belt and vacuum)

- Re-designed vacuum applicator; flexible cup has now been designed into the sleeve
- Improved electrical interconnect between sleeve and applicator for improved reliability
- (b) (4) (b)(4)
- Integrated (all-in-one) interface between control unit and applicator

Zeltiq AcuCool Sleeve (belt and vacuum)

- Added non-patient contact, (b) (4) (b)(4)
- (b) (4) (b)(4)
- New materials used in vacuum sleeve, including (b) (4) (b)(4)
- (b) (4) (b)(4)
- (b) (4) (b)(4)

Zeltiq Gelpad

- (b) (4) (b)(4)

Zeltiq Gel

- (b) (4) (b)(4)

The sponsor indicates that this modified Zeltiq System has the same (b)(4)

(b)(4)

(b)(4)

The modification of the device does not make any change to the technology and principles of operation. And it is determined that they are in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

4. **COMPARISON INFORMATION** (similarities and differences)

A substantial equivalence chart (page 26, K090094) is provided by the sponsor compared to its own predicate device, Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118), in the following area: indications for use, principle of operations, design features, and other features.

According to the sponsor, several of the design enhancements did give rise to a number of new risk mitigations as follows:

- (b)(4)
 -
 -
 -
 -
 -
- (b)(4)

In addition, the incorporation of updated software mitigated a number of risks. The relevant software features are:

- (b)(4)
 -
 -
 -
- (b)(4)

(b) (4)

(b)(4)

5. DESIGN CONTROL ACTIVITIES SUMMARY

The risk analysis was performed to assess the impact of the modification based on the Failure Modes Effects Analysis (FMEA). A copy of this result is provided (Attachment 2, K090094/S1).

Based on this risk analysis, the sponsor did conduct a verification test and concluded that no new risks associated with this modification compared to the predicates.

The sponsor did provide the following signed "Declaration of Conformity with Design Controls" statements (page 143, K090094):

- a. Verification and Validation Activities statement, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
- b. Manufacturing Facility statement, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use statement are provided.

7. DEFICIENCIES

The following deficiencies have been clarified by the sponsor:

Deficiencies in FDA AI letter dated February 5, 2009:

The sponsor's supplemental response (K090094/S1) to the deficiencies in the telephone hold letter dated February 5, 2009 is summarized as follows:

1) Indications for Use Statement

You stated that the Zeltiq System has the same intended use as the Zeltiq CLN1 Dermal Cooling Device (K080118). However, the indications for use statement of the Zeltiq System is not the same as that of the Zeltiq CLN1 Dermal Cooling Device predicate (K080118). You have changed the wording for the optional massage function from "for

the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite” to “for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite”. This is not acceptable for a special 510(k) submission.

- a. Please change your indications for use statement to be the same as that of your (b)(4) (b)(4) or
- b. Please provide data to support the change of the indications statement and resubmit your application as a traditional 510(k) document.

Response:

The sponsor has revised the indications for use statement to be (b)(4) (b)(4) (b)(4) Zeltiq CLN1 Dermal Cooling Device (K080118). The word “temporary” has been added to indications for the optional massage function as follows: “for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite”. This response is acceptable.

2) **Substantial Equivalence Comparison**

In the substantial equivalence device comparison chart (page 26), you include the comparison of indications for use, principle of operations, design features, and other features. You also provided a list of design enhancements for the device. However, you did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device. Please provide data and/or rationale(s) to justify that the differences shown in the substantial equivalence comparison table do not adversely affect the safety and effectiveness of your device.

Response:

The sponsor has adequately clarified the modifications made to the device. According to them, several of the design enhancements did give rise to a number of new risk mitigations as follows:

- Creating a separable upper and lower module vs. a single piece system in K080118; see risk mitigation measures COM1:DIS:32, 44, 47, 50, 51, 62, 64, 69, 71, 172 and 189.
- (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) see risk mitigation measures COM1:DIS:132, 217 and 221;
- Computer-controlled vacuum pressure vs. manual control in CLN1 dermal cooling device; see risk mitigation measures COM1:DIS:88;
- (b)(4), (b)(5) (b)(4), (b)(5) were evaluated per ISO 10993-1; see risk mitigation measures COM1:DIS:130 and 302; and
- Integrated (all-in-one) interface between control unit and applicator, which represents an improvement over a similar interface in K080118; see risk mitigation measure COM1:DIS:29.

In addition, the incorporation of updated software mitigated a number of risks. The relevant software features are:

- System error generation if the TEC voltage goes out of bounds (COM1:DIS:229);
- The use of (b)(4) (b)(4) (b)(4), (b)(5) (COM1:DIS:294);
- Removal of TEC power when the system is (b)(4), (b)(4), (b)(5) (b)(4), (b)(5) (COM1:DIS:295); and
- The implementation of a test of the system watchdog during power-on start-up testing (COM1:DIS:298).

The sponsor indicated that each of these features was tested as part of design verification and validation and met their acceptance criteria. Therefore, there is no impact to safety or effectiveness of the device associated with these additional features. This response is adequate.

3) Risk Analysis

You mentioned that the risk analysis methods used to assess the impact of the modifications included both a top down approach (System Hazard Analysis) and a bottom-up approach (Design Failure Modes and Effects Analysis) conducted per ISO 14971:2007 and Zeltiq Aesthetics procedures. However, you did not provide the results of your risk analysis. Please provide the results of your risk analysis.

Response:

(b)(4)
(b)(4)

4) Revised Labeling

The treatment profiles (page 2-10, 2-11) in your revised Zeltiq System User Manual are different from those that were cleared previously in your predicate, Zeltiq CLN1 Dermal Cooling Device (K080118).

- a. Please provide a redline copy of your Directions for Use including Zeltiq System User Manual, Zeltiq AcuCool Belt Sleeve Directions for Use, AcuCool Vacuum Sleeve Directions for Use, and Gelpad Directions for Use to show all the changes made to the previously cleared labelings in K080118.
- b. Please provide data to support the change in your proposed treatment profiles, or please change the profiles to be consistent with those in the predicate K080118.

Response:

The sponsor did not provide the redline copy of the User Manual. Instead, the sponsor provided a list comparison of system directions for use (Table 1, Attachment 3, K090094/S1). However, following proposed changes are not acceptable:

- (b)(4)
-
- (b)(4)

Further clarifications are needed. See new deficiencies #1-7.

New Deficiencies in FDA AI letter dated March 4, 2009:

In this supplement (K090094/S2 dated 5/8/2009), the sponsor has adequately addressed all the deficiencies in the telephone hold letter dated March 4, 2009 as follows:

- 1) In your response to deficiency #4b in FDA's AI letter dated February 5, 2009, you indicated the use of CIF (the rate of heat extraction), time and message to describe the "profile". However, please note that your device was cleared based on (b)(4)

(b)(4)

(b)(4)

- a. Please provide more information regarding the use of CIF index, its definition, and/or calculation formula to demonstrate the use of CIF can indeed be meaningful and representative.

b. (b)(4)

(b)(4)

Response:

(b)(4)

(b)(4)

Profile	Treatment Level Description
	(b)(4)
1	(b)(4)
2	

Profile	Treatment Level Description
	(b) (4)
3	
4	
5	(b)(4)
6	
7	

The changes are in the layout of the table that includes the recommended profiles for each of the indications as follows:

- (b) (4)
- (b)(4)
- (b)(4)
- (b)(4)

This response is adequate.

- 2) (b) (4)
- (b)(4)

Response:

(b) (4)

(b)(4)

(b)(4)
(b)(4)

From	To
(b)(4)	(b)(4)

This modification is acceptable.

3) (b)(4)
(b)(4)

Response:
(b)(4)
(b)(4)

Response:

(b) (4)

(b)(4)

Response:

(b) (4)

(b)(4)

(b)(4)

(b)(4)

This information is adequate.

6)

(b)(4)

(b)(4)

Response:

(b)(4)

(b)(4)

This response is acceptable.

7). Your revised Zeltiq System User Manual include following exculpatory languages (page 70 of 150, K090094/S1):

- “Zeltiq Aesthetics makes no warranty, expressed or implied, with regard to the content of its user documentation including but not limited to warranty of fitness for a particular purpose” and
- “Zeltiq Aesthetics shall not be liable for errors contained in its user documentation or for damages that might arise in connection with the furnishing, performance, or use of this material”.

This is not acceptable. Please remove any exculpatory language that is intended to release the sponsor from liability for negligence.

Response:

(b) (4)

(b)(4)

RECOMMENDATION:

The labeling for this modified subject device has been reviewed to verify that the indications/intended use for the device is appropriate. In addition, the sponsor's description of the Zeltiq System and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed.

The sponsor has provided the design control information as specified in The New 510(k) Paradigm and, on this basis, I recommend the subject device, "Zeltiq System" be determined substantially equivalent to the previously cleared their own predicate device, Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118).

SE is recommended.

Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Instrument, Surgical, Powered
Regulatory Class: Class II
Product Code: GEX
Additional Product Code: ILO, ISA



5/18/09

Long H. Chen, Ph.D.
General and Surgical Devices Branch
Division of Surgical, Orthopaedic and Restorative Devices

I concur with SE

5/19/09

CONTACT HISTORY:

A telephone message was left with the sponsor (Mr. Donald V Johnson) on 2/5/2009 asking for additional information, followed by the e-mail.

An e-mail was sent to the sponsor (Mr. Donald V Johnson) on 3/4/2009 asking for additional information.

Further clarification with the sponsor (Mr. Donald V Johnson) on 3/13, and 3/23/2009.

A telephone discussion with the sponsor on their draft response on 3/24/2009

Further comments on sponsor's draft response on 3/30, 4/16, and 4/23/2009.

Chen, Long H

From: Chen, Long H
Sent: Thursday, April 23, 2009 4:14 PM
To: 'Bryan Olin'; Donald Johnson
Subject: RE: Response to K090094

Don,

As mentioned earlier, here are our comments for your considerations:

- 1) please provide your design document for the implementation of treatment profiles 1 through 7 and shutdown limits (target temperature in degree C, treatment duration in minutes, vacuum pressure in inches of Hg and massage status) to demonstrate that your device is designed based on pre-determined profiles same as those in the predicate.
- 2) your proposed modified statement is acceptable.
- 3) your clarification is acceptable
- 4) there is no need to change the statement as long as design document is provided to demonstrate the implementation of temperature limits
- 5) please provide a copy of the revised user manual for review
- 6) see comments #1, please provide design document to demonstrate the implementation of vacuum pressure limits
- 7) please provide a copy of the revised user manual for review

Let me know if you have more questions. Thanks.

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Bryan Olin [mailto:(b)(4)]
Sent: Monday, March 30, 2009 6:18 PM
To: Chen, Long H
Cc: Donald Johnson
Subject: Response to K090094

Dr. Chen-

Attached please find responses to your questions based on our discussion last week. Don Johnson is out the remainder of this week so should you have any questions please do not hesitate to contact me at the number below.

Please let us know if you find these responses acceptable and whether you would like us to send hard copies to the Document Control office at CDRH.

Regards,

Bryan

Bryan Olin, Ph.D.
Senior Director, Quality Assurance
Zeltiq Aesthetics
4698 Willow Road
Pleasanton, CA 94588

(b)(4)
(b)(4)

The information in this email (including any attachments) may be privileged and/or confidential and is intended only for the recipient(s) listed above. Any use, disclosure, distribution or copying of this email is prohibited except by or on behalf of the intended recipient. If you have received this email in error, please notify me immediately and destroy all copies of the transmittal. Thank you.

Chen, Long H

From: Donald Johnson (b) (4) (b)(4)
Sent: Tuesday, March 24, 2009 12:32 PM
To: Chen, Long H
Subject: RE: Draft Response to 510k Questions (K090094/S1)

Dr. Chen,

That time works well for us. I will call your office at 2:30pm EST today. With you on the phone from this end will be the following:

1. Me
2. Bryan Olin- Sr. Quality Director
3. John Allison, PhD- VP of R&D
4. Mitch Levinson- President and CEO

We are looking forward to a production discussion.

Don

From: Chen, Long H [mailto:Long.Chen@fda.hhs.gov]
Sent: Tuesday, March 24, 2009 7:26 AM
To: Donald Johnson
Subject: RE: Draft Response to 510k Questions (K090094/S1)

Don,

I would be available for discussion this afternoon from 2:30pm-3:00pm EST.

Long
 Long Chen, Ph.D.
 (240)276-3628
 GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Donald Johnson [mailto:(b) (4) (b)(4)]
Sent: Monday, March 23, 2009 4:43 PM
To: Chen, Long H
Subject: RE: Draft Response to 510k Questions (K090094/S1)

Dear Dr. Chen,

I would like to set up a call with you to discuss your comments below. Let me know when would be a good time for you and I will plan the call around your schedule.

Regards,
 Don Johnson

From: Chen, Long H [mailto:Long.Chen@fda.hhs.gov]
Sent: Monday, March 23, 2009 11:07 AM
To: Donald Johnson
Subject: RE: Draft Response to 510k Questions (K090094/S1)

Don,

Here are our comments for your considerations:

(b)(4)

(b)(4)

7) OK

Let me know if you have more questions.

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

From: Donald Johnson [mailto:[\(b\)\(4\)](mailto:(b)(4))] (b)(4)
Sent: Friday, March 13, 2009 4:02 PM
To: Chen, Long H
Subject: Draft Response to 510k Questions

Dear Dr. Chen,

Attached is our draft response to the questions you forwarded on 3/4/09. This draft does not include the changes to the User Manual. After we have had an opportunity to discuss this response, we will make any necessary changes and submit the formal response through the Document Mail Center. Let me know when would be a good time for us to schedule a time to discuss this response with you.

Sincerely,
Don Johnson

Donald V. Johnson
Vice-President, Operations
Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

(b)(4)

(b)(4)

COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen

Subject: 510(k) Number K090094/S1

To: The Record

Please list CTS decision code AZ

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

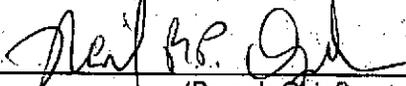
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?		X	
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< .18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
nanotechnology			X

ev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		

Regulation Number 21CFR 878.4810 Class* II Product Code GEX
(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review:  9503 3/5/04
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

TO: THE FILE

RE: DOCUMENT NUMBER **K090094/S1**

DATE: March 4, 2009

OFFICE: HFZ-410

FROM: Long Chen, Ph.D. Chemical Engineer

DIVISION: DGRND/GSDB

DEVICE NAME: Zeltiq System

COMPANY NAME: Zeltiq Aesthetics
Pleasanton, CA

CONTACT: Donald V Johnson

VP Operations, Regulatory, & Quality Affairs

(b)(4), (b)(5)

(b)(4), (b)(5)

This 510(k) submission contains information/data on modifications made to the sponsor's own Class II devices. The following items are presented:

1. NAME, 510(k) NUMBER AND PREDICATES:

The sponsor's previously cleared predicate device for this submission is:
Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118).

2. INDICATIONS FOR USE

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, and for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

This **INDICATION/INTENDED USE** of the modified device **HAS NOT CHANGED**.

However, the proposed Zeltiq System User Manual contains changes that need to be further clarified by the sponsor. See new deficiency #1.

142

3. MODIFICATION(S) OF THE DEVICE

The Zeltiq System is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It consists of the following components: Zeltiq breeze control unit, Zeltiq breeze applicator (belt and vacuum styles are available), Zeltiq AcuCool sleeve (belt and vacuum styles are available), Zeltiq Gelpad, and Zeltiq Gel.

According to the sponsor, the modifications are in the following:

Zeltiq Breeze Control Unit (incl. software)

- Improved industrial design of unit
- Redesign umbilical support arm for improved ergonomics
- Separable upper and lower modules
- Increased size of touch screen display
- Integrated (all-in-one) interface between control unit and applicator
- (b) (4), (b) (5)
- (b)(4), (b)(5)
- Adjustable voltage power supply (to support future applicators)
- (b) (4) (b)(4)
- Updated software and enhanced graphical user interface
 - Improved control algorithm
 - Patient call functionality
 - Improved error handling

Zeltiq Breeze Applicator (belt and vacuum)

- Re-designed vacuum applicator; flexible cup has now been designed into the sleeve
- Improved electrical interconnect between sleeve and applicator for improved reliability
- (b) (4), (b) (5) (b)(4), (b)(5)
- Integrated (all-in-one) interface between control unit and applicator

Zeltiq AcuCool Sleeve (belt and vacuum)

- (b) (4) (b)(4)
- New materials used in vacuum sleeve, (b) (4) (b)(4)
- (b) (4) (b)(4)

Zeltiq Gelpad

- (b) (4) (b)(4)

Zeltiq Gel

- (b) (4) (b)(4)

The sponsor indicates that this modified Zeltiq System has the (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

4. COMPARISON INFORMATION (similarities and differences)

A substantial equivalence chart (page 26, K090094) is provided by the sponsor compared to its own predicate device, Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118), in the following area: indications for use, principle of operations, design features, and other features.

According to the sponsor, several of the design enhancements did give rise to a number of new risk mitigations as follows:

• (b)(4), (b)(5)

(b)(4), (b)(5)

In addition, the incorporation of updated software mitigated a number of risks. The relevant software features are:

• (b)(4), (b)(5)

(b)(4), (b)(5)

The sponsor indicated that each of these features was tested as part of design verification and validation and met their acceptance criteria. Therefore, there is no impact to safety or effectiveness of the device associated with these additional features.

5. DESIGN CONTROL ACTIVITIES SUMMARY

The risk analysis was performed to assess the impact of the modification based on the Failure Modes Effects Analysis (FMEA). A copy of this result is provided (Attachment 2, K090094/S1).

Based on this risk analysis, the sponsor did conduct a verification test and concluded that no new risks associated with this modification compared to the predicates.

The sponsor did provide the following signed "Declaration of Conformity with Design Controls" statements (page 143, K090094):

- a. Verification and Validation Activities statement, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
- b. Manufacturing Facility statement, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

6. A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use statement are provided.

RECOMMENDATION:

The sponsor's supplemental response to the deficiencies in the telephone hold letter dated February 5, 2009 is inadequate and is summarized as follows

1) Indications for Use Statement

You stated that the Zeltiq System has the same intended use as the Zeltiq CLN1 Dermal Cooling Device (K080118). However, the indications for use statement of the Zeltiq System is not the same as that of the Zeltiq CLN1 Dermal Cooling Device predicate (K080118). You have changed the wording for the optional massage function from "for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite" to "for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite". This is not acceptable for a special 510(k) submission.

- a. Please change your indications for use statement to be the same as that of your Zeltiq CLN1 Dermal Cooling Device predicate; or
- b. Please provide data to support the change of the indications statement and resubmit your application as a traditional 510(k) document.

Response:

(b)(4), (b)(5)

(b)(4), (b)(5)

2) Substantial Equivalence Comparison

In the substantial equivalence device comparison chart (page 26), you include the comparison of indications for use, principle of operations, design features, and other features. You also provided a list of design enhancements for the device. However, you did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device. Please provide data and/or rationale(s) to justify that the differences shown in the substantial equivalence comparison table do not adversely affect the safety and effectiveness of your device.

Response:

The sponsor has adequately clarified the modifications made to the device. According to them, several of the design enhancements did give rise to a number of new risk mitigations as follows:

- Creating a separable upper and lower module vs. a single piece system in K080118; see risk mitigation measures COM1:DIS:32, 44, 47, 50, 51, 62, 64, 69, 71, 172 and 189.
- (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5) see risk mitigation measures COM1:DIS:132, 217 and 221;
- Computer-controlled vacuum pressure vs. manual control in CLN1 dermal cooling device; see risk mitigation measures COM1:DIS:88;
- (b)(4), (b)(5) (b)(4), (b)(5) were evaluated per ISO 10993-1; see risk mitigation measures COM1:DIS:130 and 302; and
- Integrated (all-in-one) interface between control unit and applicator, which represents an improvement over a similar interface in K080118; see risk mitigation measure COM1:DIS:29.

In addition, the incorporation of updated software mitigated a number of risks. The relevant software features are:

- System error generation if the TEC voltage goes out of bounds (COM1:DIS:229);
- The use of (b)(4), (b)(5) (b)(4), (b)(5)
(b)(4), (b)(5) (b)(4), (b)(5) (COM1:DIS:294);
- Removal of TEC power when the system is (b)(4), (b)(5) (b)(4), (b)(5) (b)(4), (b)(5) (COM1:DIS:295); and
- The implementation of a test of the system watchdog during power-on start-up testing (COM1:DIS:298).

The sponsor indicated that each of these features was tested as part of design verification and validation and met their acceptance criteria. Therefore, there is no impact to safety or effectiveness of the device associated with these additional features. This response is adequate.

3) Risk Analysis

You mentioned that the risk analysis methods used to assess the impact of the modifications included both a top down approach (System Hazard Analysis) and a bottom-up approach (Design Failure Modes and Effects Analysis) conducted per ISO 14971:2007 and Zeltiq Aesthetics procedures. However, you did not provide the results of your risk analysis. Please provide the results of your risk analysis.

Response:

The sponsor has provided the DR-10990, COM1 SHA (SHA=System Hazard Analysis) and DR-10991, COM1 FMEA in Attachment 2. According to the sponsor, all identified risks have been mitigated to a level that is acceptable.

4) Revised Labeling

The treatment profiles (page 2-10, 2-11) in your revised Zeltiq System User Manual are different from those that were cleared previously in your predicate, Zeltiq CLN1 Dermal Cooling Device (K080118).

- a. Please provide a redline copy of your Directions for Use including Zeltiq System User Manual, Zeltiq AcuCool Belt Sleeve Directions for Use, AcuCool Vacuum Sleeve Directions for Use, and Gelpad Directions for Use to show all the changes made to the previously cleared labelings in K080118.

b. (b)(4), (b)(5)

(b)(4), (b)(5)

Response:

(b)(4), (b)(5)

(b)(4), (b)(5)

Further clarifications are needed. See new deficiencies #1-7.

New Deficiencies:

Consequently, new deficiencies will need to be clarified by the sponsor. They are summarized as follows:

- 1) In your response to deficiency#4b in FDA's AI letter dated February 5, 2009, you indicated the use of CIF (the rate of heat extraction), time and message to describe the "profile". However, please note that your device was cleared based on (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

- a. Please provide more information regarding the use of CIF index, its definition, and/or calculation formula to demonstrate the use of CIF can indeed be meaningful and representative.

b. (b)(4), (b)(5)
(b)(4), (b)(5)

2) (b)(4), (b)(5)
(b)(4), (b)(5)

3) (b)(4), (b)(5)
(b)(4), (b)(5)

4) (b)(4), (b)(5)
(b)(4), (b)(5)

5) (b)(4), (b)(5)
(b)(4), (b)(5)

(b)(4), (b)(5)

6)

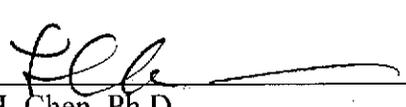
(b)(4), (b)(5)

7) Your revised Zeltiq System User Manual include following exculpatory languages (page 70 of 150, K090094/S1):

- “Zeltiq Aesthetics makes no warranty, expressed or implied, with regard to the content of its user documentation including but not limited to warranty of fitness for a particular purpose” and
- “Zeltiq Aesthetics shall not be liable for errors contained in its user documentation or for damages that might arise in connection with the furnishing, performance, or use of this material”.

This is not acceptable. Please remove any exculpatory language that is intended to release the sponsor from liability for negligence.

The sponsor, Mr. Donald V Johnson, was informed on March 4, 2009 that the subject submission, K090094/S1, will be placed on telephone hold until the above referenced additional information is received by FDA. I, therefore, recommend that this submission be placed on hold pending receipt of the response to the above questions.


 Long H. Chen, Ph.D.
 General and Surgical Devices Branch
 Division of General, Restorative, and Neurological Devices

3/4/09

If answer with AT requests

Neil 3/5/09

CONTACT HISTORY: A telephone message was left with the sponsor (Mr. Donald V Johnson) on 2/5/2009 asking for additional information, followed by the e-mail. An e-mail was sent to the sponsor (Mr. Donald V Johnson) on 3/4/2009 asking for additional information.

Chen, Long H

From: Chen, Long H
Sent: Wednesday, March 04, 2009 3:55 PM
To: (b) (4) (b)(4)
Subject: Special 510(k) supplement - Zeltiq System (K090094/S1)
Attachments: k090094.s1_email.1.doc

Don,

I have enclosed a copy of the additional information request for the subject 510 (k) supplement. Feel free to contact me for any further clarification. Thanks.



k090094.s1_email.1.doc (43 K)

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

March 4, 2009

Mr. Donald V Johnson
VP Operations, Regulatory, & Quality Affairs
Zeltiq Aesthetics, Pleasanton, CA

Ph#: (b)(4), (b)(5)

Fax#: (b)(4), (b)(5)

e-mail: (b)(4), (b)(5)

Re: Special 510(k) supplement - Zeltiq System (K090094/S1)

Dear Mr. Johnson,

In reviewing the subject supplement, we have the following additional questions that need to be clarified to facilitate our review process:

- 1) In your response to deficiency#4b in FDA's AI letter dated February 5, 2009, you indicated the use of CIF (the rate of heat extraction), time and message to describe the "profile". However, please note that your device was cleared based on (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

- a. Please provide more information regarding the use of CIF index, its definition, and/or calculation formula to demonstrate the use of CIF can indeed be meaningful and representative.

- b. (b)(4), (b)(5)

(b)(4), (b)(5)

- 2) (b)(4), (b)(5)

(b)(4), (b)(5)

- 3)

(b)(4), (b)(5)

4)

5)

(b)(4), (b)(5)

6)

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(b)(4), (b)(5)

(b)(4), (b)(5)

7) Your revised Zeltiq System User Manual include following exculpatory languages (page 70 of 150, K090094/S1):

- “Zeltiq Aesthetics makes no warranty, expressed or implied, with regard to the content of its user documentation including but not limited to warranty of fitness for a particular purpose” and
- “Zeltiq Aesthetics shall not be liable for errors contained in its user documentation or for damages that might arise in connection with the furnishing, performance, or use of this material”.

This is not acceptable. Please remove any exculpatory language that is intended to release the sponsor from liability for negligence.

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request. For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at: http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

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COVER SHEET MEMORANDUM

From: Reviewer Name Long Chen
Subject: 510(k) Number 10090094
To: The Record

Please list CTS decision code AZ

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information of Telephone Hold)
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age<=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18 years old)			X
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			X
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			X
Nanotechnology			X

**SPECIAL 510(k): Device Modification
ODE Review Memorandum**

TO: THE FILE

RE: DOCUMENT NUMBER **K090094**

DATE: February 5, 2009

OFFICE: HFZ-410

FROM: Long Chen, Ph.D. Chemical Engineer

DIVISION: DGRND/GSDB

DEVICE NAME: Zeltiq System

COMPANY NAME: Zeltiq Aesthetics
Pleasanton, CA

CONTACT: Donald V Johnson
VP Operations, Regulatory, & Quality Affairs
(Tel: (b)(4), (b)(5), (b)(4), (b)(5))
e-mail: (b)(4), (b)(5)

This 510(k) submission contains information/data on modifications made to the sponsor's own Class II devices. The following items are presented:

1. NAME, 510(k) NUMBER AND PREDICATES:

The sponsor's previously cleared predicate device for this submission is:
Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118).

2. INDICATIONS FOR USE

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that include minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite.

The Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

The sponsor claimed that **INDICATION/INTENDED USE** of the modified device **HAS NOT CHANGED**. However, the sponsor changed the wording for the optional massage function from "for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite" to "for the relief of minor muscle aches, pain, and spasm, and for the

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improvement in local circulation and temporary reduction in the appearance of cellulite".
See deficiency #1.

3. MODIFICATION(S) OF THE DEVICE

The Zeltiq System is a thermoelectric device that applies a user selected treatment profile in a controlled manner to a treatment site. It consists of the following components: Zeltiq breeze control unit, Zeltiq breeze applicator (belt and vacuum styles are available), Zeltiq acuCool sleeve (belt and vacuum styles are available), Zeltiq Gelpad, and Zeltiq Gel.

According to the sponsor, the modifications are in the following:

Zeltiq Breeze Control Unit (incl. software)

- Improved industrial design of unit
- Redesign umbilical support arm for improved ergonomics
- Separable upper and lower modules
- Increased size of touch screen display
- Integrated (all-in-one) interface between control unit and applicator
- (b)(4), (b)(5)
(b)(4), (b)(5)
- Adjustable voltage power supply (to support future applicators)
- (b)(4), (b)(5) (b)(4), (b)(5)
- Updated software and enhanced graphical user interface
 - Improved control algorithm
 - Patient call functionality
 - Improved error handling

Zeltiq Breeze Applicator (belt and vacuum)

- Re-designed vacuum applicator; flexible cup has now been designed into the sleeve
- Improved electrical interconnect between sleeve and applicator for improved reliability
- (b)(4), (b)(5) (b)(4), (b)(5)
- Integrated (all-in-one) interface between control unit and applicator

Zeltiq AcuCool Sleeve (belt and vacuum)

- (b)(4), (b)(5)
(b)(4), (b)(5)
- New materials used in vacuum sleeve, including (b)(4), (b)(5)
- (b)(4), (b)(5)
(b)(4), (b)(5)

Zeltiq Gelpad

- (b)(4), (b)(5) (b)(4), (b)(5)

Zeltiq Gel

- (b)(4), (b)(5)

The sponsor indicates that this modified Zeltiq System (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

4. **COMPARISON INFORMATION** (similarities and differences)

A substantial equivalence chart (page 26) is provided by the sponsor compared to its own predicate device, Zeltiq Aesthetics CLN1 Dermal Cooling Device (K080118), in the following area: indications for use, principle of operations, design features, and other features.

The sponsor also provided a list of design enhancements for the modification. However, the sponsor did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device.

5. **DESIGN CONTROL ACTIVITIES SUMMARY**

The sponsor did not provide the risk analysis result. Although, the sponsor did indicate that the results of the risk analysis were the risk control measures identified for the required verification and validation as shown in Table 6 (page 139).

The sponsor did provide a signed "Declaration of Conformity with Design Controls" statements (page 143).

6. **A Truthful and Accurate Statement, a 510(k) Summary and the Indications for Use statement are provided.**

RECOMMENDATION:

The subject submission will be placed on hold pending upon the following additional information:

1) Indications for Use Statement

You stated that the Zeltiq System has the same intended use as the Zeltiq CLN1 Dermal Cooling Device (K080118). However, the indications for use statement of the Zeltiq System is not the same as that of the Zeltiq CLN1 Dermal Cooling Device predicate (K080118). You have changed the wording for the optional massage function from "for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite" to "for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite". This is not acceptable for a special 510(k) submission.

- a. Please change your indications for use statement to be the same as that of your Zeltiq CLN1 Dermal Cooling Device predicate; or
- b. Please provide data to support the change of the indications statement and resubmit your application as a traditional 510(k) document.

2) Substantial Equivalence Comparison

In the substantial equivalence device comparison chart (page 26), you include the comparison of indications for use, principle of operations, design features, and other features. You also provided a list of design enhancements for the device. However, you did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device. Please provide data and/or rationale(s) to justify that the differences shown in the substantial equivalence comparison table do not adversely affect the safety and effectiveness of your device.

3) Risk Analysis

You mentioned that the risk analysis methods used to assess the impact of the modifications included both a top down approach (System Hazard Analysis) and a bottom-up approach (Design Failure Modes and Effects Analysis) conducted per ISO 14971:2007 and Zeltiq Aesthetics procedures. However, you did not provide the results of your risk analysis. Please provide the results of your risk analysis.

4) Revised Labeling

The treatment profiles (page 2-10, 2-11) in your revised Zeltiq System User Manual are different from those that were cleared previously in your predicate, Zeltiq CLN1 Dermal Cooling Device (K080118).

- a. Please provide a redline copy of your Directions for Use including Zeltiq System User Manual, Zeltiq AcuCool Belt Sleeve Directions for Use, AcuCool Vacuum Sleeve Directions for Use, and Gelpad Directions for Use to show all the changes made to the previously cleared labelings in K080118.

- b. (b)(4), (b)(5)

(b)(4), (b)(5)

The sponsor, Mr. Donald V Johnson, was informed on February 5, 2009 that the subject submission, K090094, will be placed on telephone hold until the above referenced additional information is received by FDA. I, therefore, recommend that this submission be placed on hold pending receipt of the response to the above questions.

llc 2/5/09

Long H. Chen, Ph.D.
 General and Surgical Devices Branch
 Division of General, Restorative, and Neurological Devices

I concur with AL
Neil 2/5/09

CONTACT HISTORY: A telephone message was left with the sponsor (Mr. Donald V Johnson) on 2/5/2009 asking for additional information, followed by the e-mail.

Chen, Long H

From: Chen, Long H
Sent: Thursday, February 05, 2009 8:43 AM
To: (b) (4), (b) (5)
Subject: Special 510(k) submission - Zeltiq System (K090094)

Attachments: k090094_email.1.doc

Don,

I have enclosed a copy of the additional information request for the subject 510 (k) submission. Feel free to contact me for any further clarification. Thanks.



k090094_email.1.doc (38 KB)

Long
Long Chen, Ph.D.
(240)276-3628
GSDB/DGRND/ODE/FDA
long.chen@fda.hhs.gov

February 5, 2009

Mr. Donald V Johnson
VP Operations, Regulatory, & Quality Affairs
Zeltiq Aesthetics, Pleasanton, CA

Ph#: (b) (4), (b) (5) (5)

Fax#: (b) (4), (b) (5) (5)

e-mail: (b) (4), (b) (5) (5)

Re: Special 510(k) submission - Zeltiq System (K090094)

Dear Mr. Johnson,

In reviewing the subject submission, we have the following additional questions that need to be clarified to facilitate our review process:

1) Indications for Use Statement

You stated that the Zeltiq System has the same intended use as the Zeltiq CLN1 Dermal Cooling Device (K080118). However, the indications for use statement of the Zeltiq System is not the same as that of the Zeltiq CLN1 Dermal Cooling Device predicate (K080118). You have changed the wording for the optional massage function from "for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite" to "for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite". This is not acceptable for a special 510(k) submission.

- a. Please change your indications for use statement to be the same as that of your Zeltiq CLN1 Dermal Cooling Device predicate; or
- b. Please provide data to support the change of the indications statement and resubmit your application as a traditional 510(k) document.

2) Substantial Equivalence Comparison

In the substantial equivalence device comparison chart (page 26), you include the comparison of indications for use, principle of operations, design features, and other features. You also provided a list of design enhancements for the device (page 24). However, you did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device. Please provide data and/or rationale(s) to justify that the differences shown in the substantial equivalence comparison table do not adversely affect the safety and effectiveness of your device.

3) Risk Analysis

You mentioned that the risk analysis methods used to assess the impact of the modifications included both a top down approach (System Hazard Analysis) and a

bottom-up approach (Design Failure Modes and Effects Analysis) conducted per ISO 14971:2007 and Zeltiq Aesthetics procedures. However, you did not provide the results of your risk analysis. Please provide the results of your risk analysis.

4) Revised Labeling

The treatment profiles (page 2-10, 2-11) in your revised Zeltiq System User Manual are different from those that were cleared previously in your predicate, Zeltiq CLN1 Dermal Cooling Device (K080118).

- a. Please provide a redline copy of your Directions for Use including Zeltiq System User Manual, Zeltiq AcuCool Belt Sleeve Directions for Use, AcuCool Vacuum Sleeve Directions for Use, and Gelpad Directions for Use to show all the changes made to the previously cleared labelings in K080118.

b. (b)(4), (b)(5)

(b)(4), (b)(5)

The subject submission will be placed on hold pending your response with the requested information. If you need more than 30 days to provide a full and complete response, you should submit a request for an extension of time to Document Mail Center (HFZ 401). FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request. For further information on how to apply for an extension and for general 510(k) information, please visit the FDA Website at: http://www.fda.gov/cdrh/devadvice/31435.html#link_6

Sincerely,

Long Chen, Ph.D.
Chemical Engineer
Phone#: (240)276-3600, Fax#: (240)276-3733
General and Surgical Devices Branch
Division of General, Restorative and Neurological Devices
FDA/ODE

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.



February 17, 2009

ZELTIQ AESTHETICS
4698 WILLOW ROAD
PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON

510k Number: K090094

Product: ZELTIQ SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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FEB 17 2009

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		<div style="border: 1px solid black; padding: 2px; display: inline-block;"> Received </div>	Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.	
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET				
Date of Submission 02/16/2009		User Fee Payment ID Number MD6040736-956733		FDA Submission Document Number (if known) K090094 / 51
SECTION A TYPE OF SUBMISSION				
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):
Have you used or cited Standards in your submission? <input type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)				
SECTION B SUBMITTER, APPLICANT OR SPONSOR				
Company / Institution Name Zeltiq Aesthetics, Inc.		Establishment Registration Number (if known) 3007215625		
Division Name (if applicable)		Phone Number (including area code) ((b) (4))		
Street Address 4698 Willow Road		FAX Number (including area code) ((b) (4))		
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA	
Contact Name Donald V. Johnson				
Contact Title Vice President, Operations, Regulatory and Quality Affairs		Contact E-mail Address ((b) (4))		
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)				
Company / Institution Name				
Division Name (if applicable)		Phone Number (including area code) ()		
Street Address		FAX Number (including area code) ()		
City	State / Province	ZIP/Postal Code	Country	
Contact Name				
Contact Title		Contact E-mail Address		

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

PSC Graphics: (301) 443-1090 EF

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software /Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE		
<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design /Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)		
<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (specify): Response to 2/5/2009 request for additional information.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	2	3	4	<input type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
5	6	7	8		

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1	1	1
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Trade or Proprietary or Model Name for This Device	Model Number
1 Zeltiq System	1
2	2
3	3
4	4
5	5

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

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

Data Included in Submission

Laboratory Testing
 Animal Trials
 Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (if applicable)	Device Class
Classification Panel		<input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified

Indications (from labeling)

<i>Note:</i> Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	
<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ()	
Street Address		FAX Number (including area code) ()	
City	State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
 CDRH (HFZ-342)
 9200 Corporate Blvd.
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control



February 16, 2009

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

RE: Supplement 1 to K090094, Zeltiq System

Dear Dr. Chen:

The letter is in response to a request for additional information presented by FDA in an e-mail dated February 5, 2009. Responses to each of the issues are included with this letter.

We trust that the information is sufficient to continue with review of the submission and appreciate your timely response. If there are any further questions, or if additional information is required, please do not hesitate to contact me at (b) (6) (b)(4) or by email at (b) (4) (b)(4)

Sincerely,

Donald V. Johnson
Vice-President of Operations, Regulatory and Quality Affairs

1) Indications for Use Statement

You stated that the Zeltiq System has the same intended use as the Zeltiq CLN1 Dermal Cooling Device (K080118). However, the indications for use statement of the Zeltiq System is not the same as that of the Zeltiq CLN1 Dermal Cooling Device predicate (K080118). You have changed the wording for the optional massage function from "for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite" to "for the relief of minor muscle aches, pain, and spasm, and for the improvement in local circulation and temporary reduction in the appearance of cellulite". This is not acceptable for a special 510(k) submission.

- a. *Please change your indications for use statement to be the same as that of your Zeltiq CLN1 Dermal Cooling Device predicate; or*
- b. *Please provide data to support the change of the indications statement and resubmit your application as a traditional 510(k) document.*

Response:

The discrepancy in the indications for use was an error that is corrected in Section 5 (Indications for Use) and Section 6 (510K Summary) of this Special 510(k) to include language identical to K080118. These are included as Attachment 1.

2) Substantial Equivalence Comparison

In the substantial equivalence device comparison chart (page 26), you include the comparison of indications for use, principle of operations, design features, and other features. You also provided a list of design enhancements for the device (page 24). However, you did not provide rationale(s) to justify that the differences in these features do not adversely affect the safety and effectiveness of the device. Please provide data and/or rationale(s) to justify that the differences shown in the substantial equivalence comparison table do not adversely affect the safety and effectiveness of your device.

Response:

The design enhancements to the Zeltiq System, as described in this Special 510(k), do not impact the indications for use, principles of operation, design features or other features listed in the substantial equivalence comparison table (Table 1 on pages 26 and 27). The design cleared under K080118 and the design under consideration in this Special 510(k) contain all the same elements as can be seen by the labeling of each of the elements as "Same" under the column K080118. There is, therefore, no affect on safety and effectiveness with respect to these elements.

Review of the potential impact on safety and effectiveness by the design enhancements otherwise listed in this Special 510(k) was completed through the design control activities and risk analysis detailed in Section 13. Several of the design enhancements did give rise to a number of new risk mitigations, as described in Section 13 of the submission and summarized below with references to line items in Table 6 of that section:

- Creating a separable upper and lower module vs. a single piece system in K080118; see risk mitigation measures COM1:DIS:32, 44, 47, 50, 51, 62, 64, 69, 71, 172 and 189.
- (b) (4) (b)(4) see risk mitigation measures COM1:DIS:132, 217 and 221;
- Computer-controlled vacuum pressure vs. manual control in CLN1 dermal cooling device; see risk mitigation measures COM1:DIS:88;
- (b) (4) (b)(4) were evaluated per ISO 10993-1; see risk mitigation measures COM1:DIS:130 and 302; and
- Integrated (all-in-one) interface between control unit and applicator, which represents an improvement over a similar interface in K080118; see risk mitigation measure COM1:DIS:29.

All of these risk mitigations met their verification and/or validation acceptance criteria and hence, there is no impact to the safety and effectiveness of the device.

In addition, the incorporation of updated software mitigated a number of risks. The relevant software features are:

- System error generation if the TEC voltage goes out of bounds (COM1:DIS:229);
- The use of (b) (4) (b)(4)
- (b) (4) (b)(4) (COM1:DIS:294);
- Removal of TEC power when the system is (b) (4) (b)(4) (COM1:DIS:295); and
- The implementation of a test of the system watchdog during power-on start-up testing (COM1:DIS:298).

Each of these features also was tested as part of design verification and validation and met their acceptance criteria as outlined in Table 6 of the submission. Therefore, there is no impact to safety or effectiveness of the device associated with these additional features.

3) Risk Analysis

You mentioned that the risk analysis methods used to assess the impact of the modifications included both a top down approach (System Hazard Analysis) and a bottom-up approach (Design Failure Modes and Effects Analysis) conducted per ISO 14971:2007 and Zeltiq Aesthetics procedures. However, you did not provide the results of your risk analysis. Please provide the results of your risk analysis.

Response:

In addition to Table 6 of Section 13 of the Special 510(k), we have provided DR-10990, COM1 SHA (SHA=System Hazard Analysis) and DR-10991, COM1 FMEA in Attachment 2. All identified risks have been mitigated to a level that is acceptable.

4) Revised Labeling

The treatment profiles (page 2-10, 2-11) in your revised Zeltiq System User Manual are different from those that were cleared previously in your predicate, Zeltiq CLN1 Dermal Cooling Device (K080118).

- a. *Please provide a redline copy of your Directions for Use including Zeltiq System User Manual, Zeltiq AcuCool Belt Sleeve Directions for Use, AcuCool Vacuum Sleeve Directions for Use, and Gelpad Directions for Use to show all the changes made to the previously cleared labelings in K080118.*

Response:

As noted in the Special 510(k), the directions for use have undergone extensive revisions intended to improve clarity, completeness and usability of the User Manual and Directions for Use. Table 5 of the submission on page 39 of 146 identifies changes to the directions for use that are specific to the design enhancements.

Additional revisions include:

- Added warnings and cautions based on an updated risk analysis. This includes a number of caution statements in Appendix B of the User Manual that were included to address IEC 60601 requirements.
- Updates to the warnings for improved readability and clarity.
- (b) (4) (b)(4) See the response to 4(b) for more details.
- To improve their effectiveness, several precautions were moved from the "Precautions" section to the point of use in the user manual. This is consistent with PL-10691 Rev E.
- Terminology changes: Zeltiq System is used in place of CLN1 Dermal Cooling device, "Caution" used in place of "Precaution" in keeping with international conventions;
- More extensive diagramming of the different parts of the control unit and applicator to aid users;

- More extensive details on paging, cleaning and maintenance;
- More extensive use of international symbols and icons on the graphical user interface and incorporation of detailed descriptions of these items;
- Incorporation of Appendix A to explain error messages; and
- Incorporation of Appendix B to identify performance characteristics and standard language associated with IEC 60601 series of electrical safety standards.

Due to the extent of the changes to the style of the directions for use and the switch from the use of Word for Windows to a desktop publishing tool, a redline copy is not practical for identification of the changes. Therefore, Attachment 3 has been provided to highlight key changes in various sections. Changes are noted in red font.

b. Please provide data to support the change in your proposed treatment profiles, or please change the profiles to be consistent with those in the predicate K080118.

Response:

There have been no changes to the treatment profiles, although presentation of the treatment profiles has been modified in both the user interface and the User's Manual.

The changes to the device's graphical user interface allow a more descriptive title for the profiles than the numbering scheme used with the CLN1 Dermal Cooling Device. The User's Manual presents the information in a format that is easier to read and incorporates the use of a cooling intensity factor (CIF) (b)(4) (b)(4). Zeltiq introduced the concept of the cooling intensity factor (CIF) to more accurately describe the mechanism of action. CIF is an index representing the rate of heat flux into or out of tissue opposite the cooling device. A positive CIF describes the rate of heat drawn from the tissue during cooling relative to 37°C. A negative CIF refers to a heat flux into the tissue during heating relative to 37°C. Belt applicators only cool tissue from one side as compared to two sides for vacuum applicators. (b)(4) (b)(4)

(b)(4)
(b)(4)

(b)(4) (b)(4) The greatest cooling capacity which can be selected with the device (b)(4) (b)(4)

(b)(4) (b)(4)

(b)(4) (b)(4) The User's Manual (PL-12689) also has been updated to include language requested by FDA in the directions for use as cleared in K080118 but that had inadvertently been omitted. The updated labeling is included in Attachment 4.

The following table is provided to aid understanding of the correspondence between the treatment profiles presented in the labeling for K080118 and this Special 510(k).

Intended Use	K080118 Dermal Cooling Device Profile Description	K090094 Profile Description: Belt	K090094 Profile Description: Vacuum
Minimize pain and thermal injury during laser and dermatological treatments	(b)(4)		
Skin cooling as a local anesthetic for procedures that induce minor local discomfort			
Localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms			
Temporary improvement in local circulation and temporary reduction in the appearance of cellulite			
Temporary relief of minor muscle aches, pain, and spasm, while utilizing the optional massage feature			

(b)(4)

(b)(4)

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Attachment 1: Revised Section 5 (Indications for Use) and Section 6 (510K Summary)

K090094

SECTION 5.

INDICATIONS FOR USE STATEMENT

5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Zeltiq System

Indications for Use:

The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

Prescription Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ___ of ___

SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

APPLICANT Zeltiq Aesthetics, Inc.
4698 Willow Road
Pleasanton, CA 94588

TRADE NAME: Zeltiq System

COMMON NAME: Skin Refrigerant

CLASSIFICATION NAME: Laser instrument, surgical, powered

DEVICE CLASSIFICATION: Class II, 21 CFR §878.4810

PRODUCT CODE 79 GEX – laser instrument, surgical, powered
89 IOL - pack, hot or cold, water circulating
89 ISA - massager, therapeutic, electric

PREDICATE DEVICE: The Zeltiq System is substantially equivalent to the Zeltiq CLN1 Dermal Cooling Device (K080118).

SUBSTANTIALLY EQUIVALENT TO:
The Zeltiq System has the same intended use and mechanism of action to the Zeltiq CLN1 Dermal Cooling Device (K080118).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The device also includes the option of electrically powered or pulsatile vacuum massage and an optional paging device.

INDICATION FOR USE:
The Zeltiq System is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include skin cooling as a local anesthetic for procedures that induce minor local discomfort. The Zeltiq System can also provide localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

SECTION 6. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Zeltiq Gel facilitates thermal contact of the Zeltiq System with a patient's skin by mitigating minor variances in device-to-skin contact.

TECHNICAL CHARACTERISTICS:

The Zeltiq System is a thermoelectric cooling and heating device that applies controlled cooling or heating to a treatment site. The optional massage feature uses electrically powered vibration or pulsatile vacuum, depending on the applicator. The system includes an optional paging device.

PERFORMANCE DATA:

Testing confirms that the Zeltiq System can be used in an equivalent manner to the predicate device.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The indications for use for the Zeltiq System are the same as for the predicate device cited in this application. A technological comparison and bench testing demonstrate that the Zeltiq System is functionally equivalent to the predicate device.

Attachment 2: DR-10990, COM1 SHA and DR-10991, COM1 FMEA

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and Justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b)(4)									

(b)(4)

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Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and Justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b) (4)									

(b)(4)

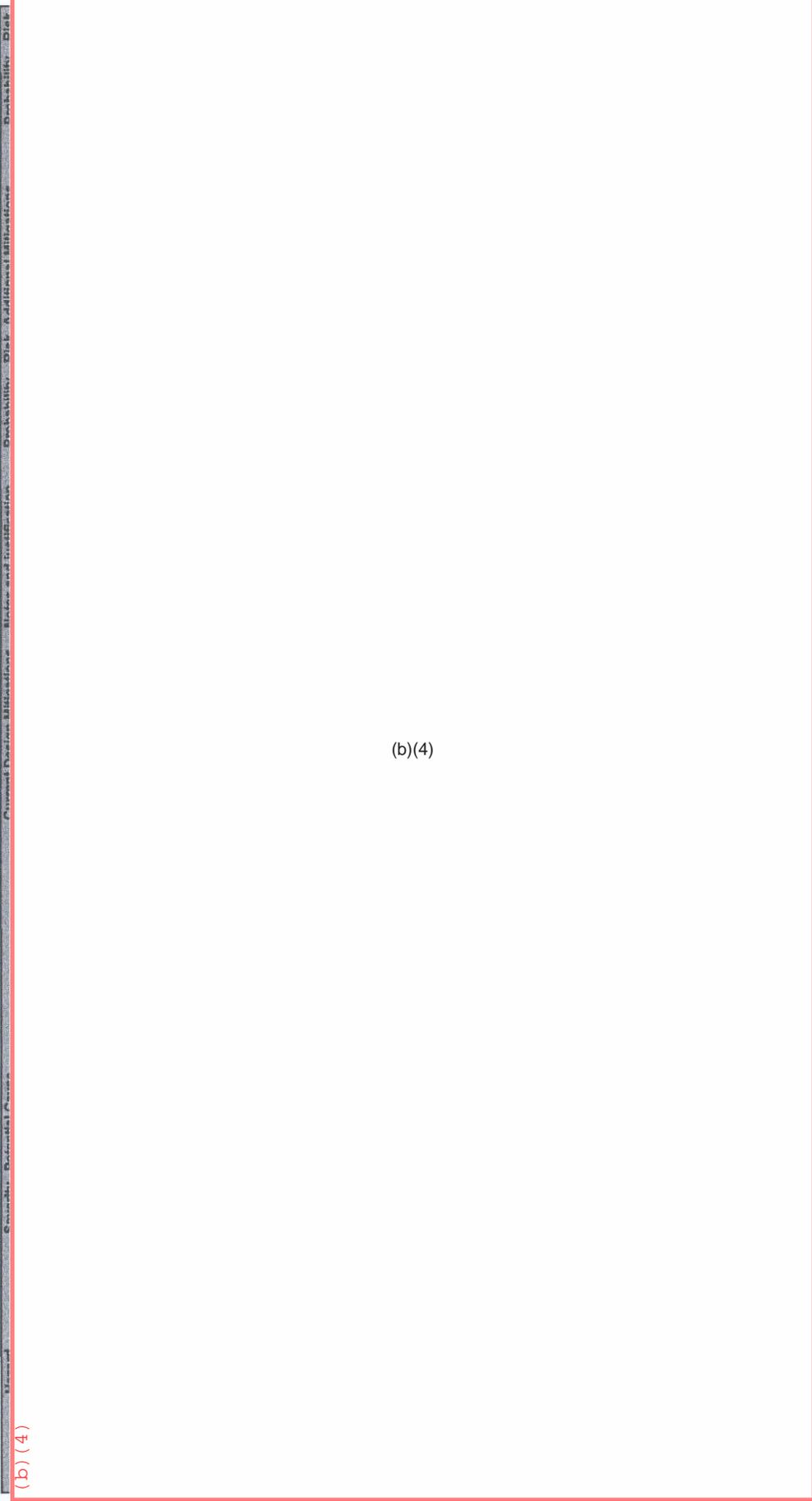
DR10990 COM1 SHA

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(b) (4)

(b)(4)

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and Justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b) (4)									

(b)(4)

Hazard	Severity	Potential Cause	Current Design Mitigations	Notes and Justification	Probability	Risk	Additional Mitigations	Probability	Risk
(b) (4)									

(b)(4)

COM 1 Design FMEA

Mode(s)	Failure	Potential Cause (origin)	Hazard	DIU/Saver Current Design Mitigation	Notes and justification	Risk Mitigation	Prob-ability	Risk	Detect-ability	Risk with Detect-ability
A1. Power Input Module and Line Filter	Electrical open - AC Mains	(b)(4)								
	Electrical short - AC Mains									
	Switch doesn't turn on / mechanical failure									
	Switch doesn't turn off / mechanical failure									
	Partial Short									
	System susceptible to line noise / surge									
	Thermal circuit breaker / fails open									
	Thermal circuit breaker / fails closed									
	AC power low									
	AC power high									
	AC power intermittent									

(b)(4)

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DR10981 FMEA, COM1

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COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	DY / Sever. Current Design Mitigations	Notes and Justification	Probab. Risk Mitigation	Probab. Risk	Detectability	Risk with Detectability
A3, PCBA, Lower Power Control	Electrical open - AC Mains or isolated AC	(b)(4)					1		
	Electrical short - Earth to isolated AC or isolated ground to line voltage	(b)(4)							
	Loss of 12VDC (Computer) power								
	Temperature sensor fails open								
	Temperature sensor fails closed								
	Failed voltage select								
	Power fuse falls prematurely								
	Fuse doesn't trip properly								
	No chiller power								
	No chiller communications								

(b)(4)

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COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/DJ/Sever/Current Design Mitigations	Notes and justification	Prob-ability	Risk	Prob-ability	Risk	Detect-ability	Risk	Detect-ability	Risk
	ID bits	(b) (4)											
A4. Power supply, computer	Voltage regulated high												
	Voltage regulated low												
	No power												
A5. Isolation transformer	Line shorted to isolated ground												
	Electrical open in mains or internal AC (no voltage)												
	Isolated voltage high												

(b)(4)

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COM 1 Design FMEA

Module	Failure	Potential Cause (Origin)	Hazard	D/O Severity	Current Design Mitigations	Notes and Justification	Prop. ability	Risk	Detectability	Risk with Detectability	
		(b) (4)									
A7.	mechanical										
	AB fluid plumbing										
	BS Control Unit B1, PCBA, Upper Power Control										

DR10991 FMEA, COM1

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K0900094 S-1

COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	DIU/Sever/Current/Design Mitigation	Notice and Justification	Probab. Risk Mitigation	Prob. ability	Risk	Defect-ability	Risk with Detect-ability
B2. Applicator Power Supply	(b) (4)	(b)(4)								
B3. Logic Power Supply										

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COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D/U Severity	Current Design Mitigations	Notes and Justification	Probability	Risk	Detectability	Risk with Detectability
	(b)(4)						4	AR		

(b)(4)

(b)(4)

COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	DU/Sover/Current Design Mitigation	Notes and Justification	Probab- ility	Risk Mitigation	Prob- ability	Risk	Detect- ability	Risk with Detect- ability
B15. Software	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

(b)(4)

(b) (4)

COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	D70 Sever Current Design Mitigations	Notes and justification	Probab- ability	Risk Mitigation	Prob- ability	Risk	Detect- ability	Risk with Detect- ability
(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)	(b) (4)

(b)(4)

(b) (4)

DR10991 FMEA, COM1

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COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	DIU/Saver Current Design Mitigation	Notes and Justification	Prob. Risk Mitigation	Probability	Risk	Detectability	Risk with Detectability
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COM 1 Design FMEA

Module	Failure	Potential Cause (origin)	Hazard	DIU Sever Current Design Mitigations	Notes and Justification	Probability	Risk Mitigation	Probability	Risk	Detect-ability	Risk with Detect-ability
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Attachment 3: Details on Labeling Changes

Table 1: Comparison of System Directions for Use

PL-10691 Rev E

PL-12689-01

Indications for Use

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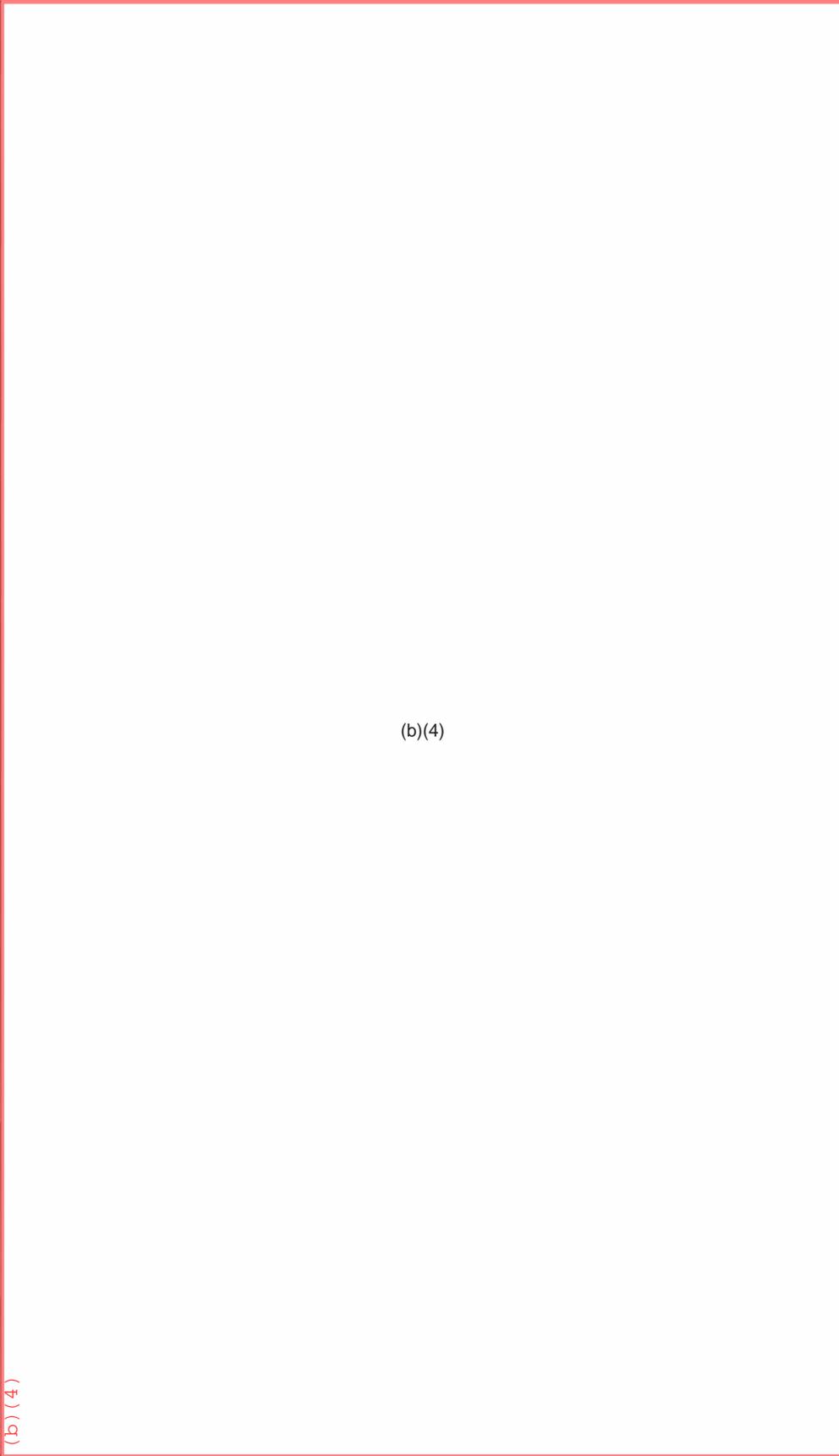
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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

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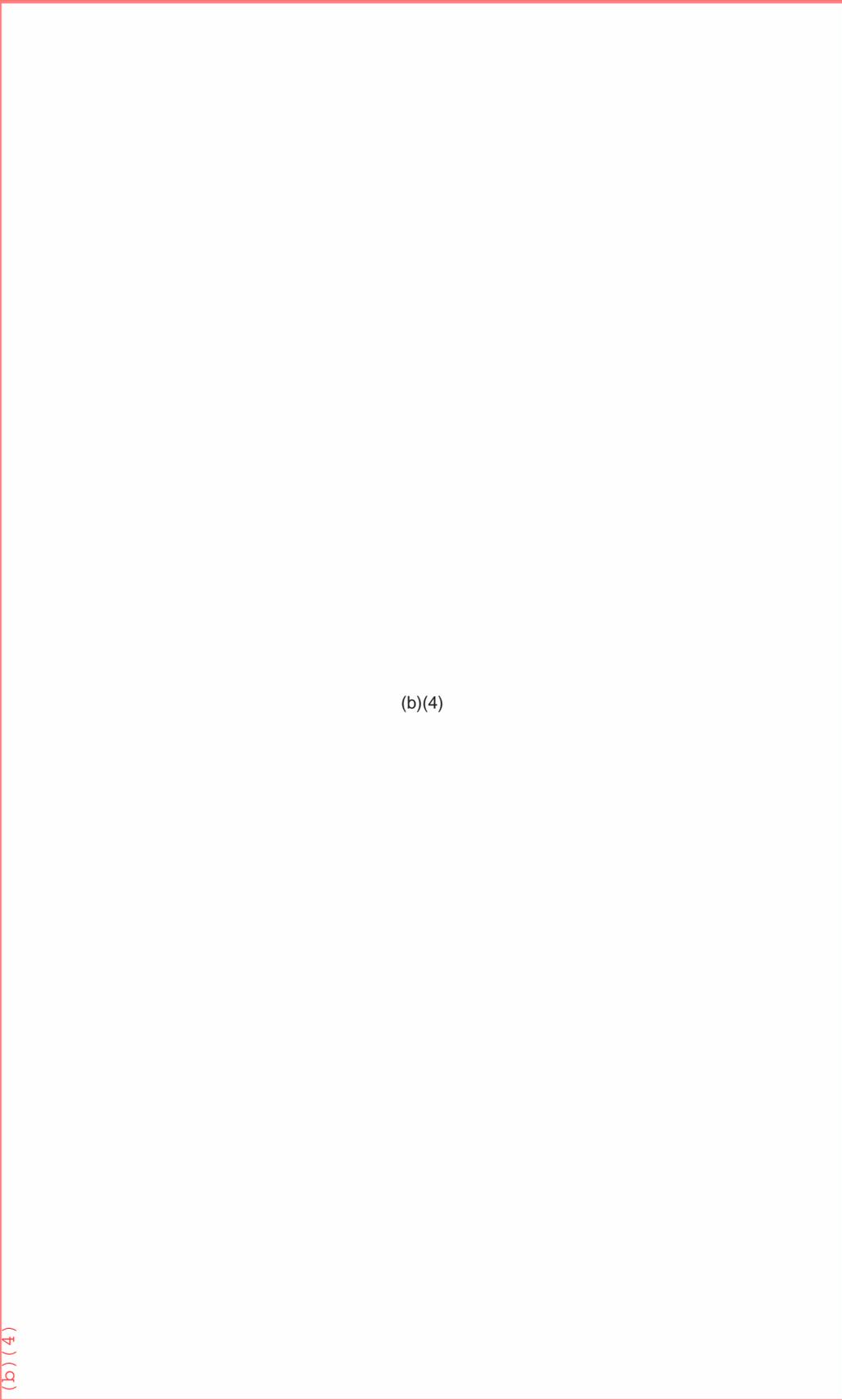
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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

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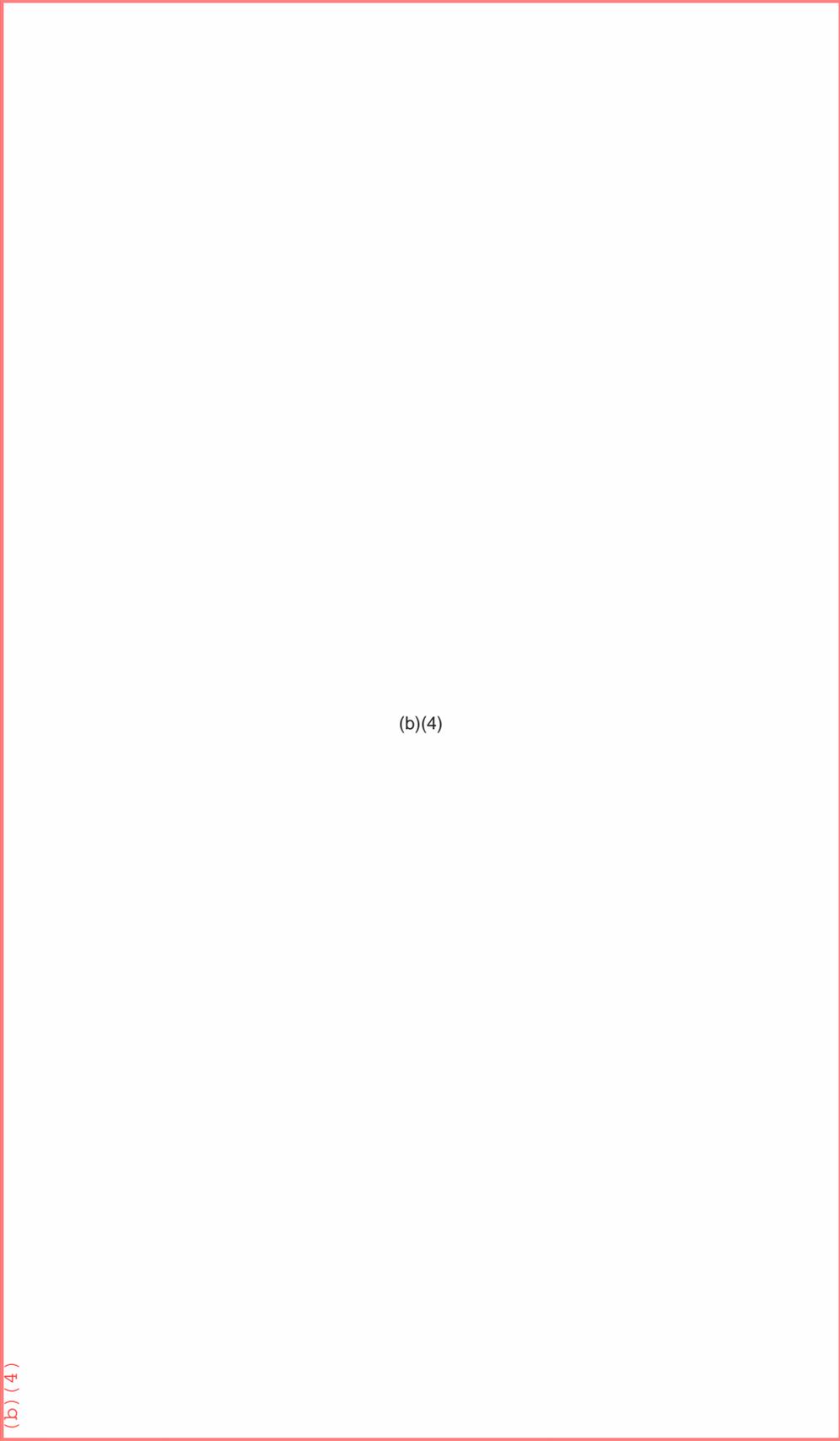
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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

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Table 1: Comparison of System Directions for Use

PL-12689-01

PL-10691 Rev E

Device Operation

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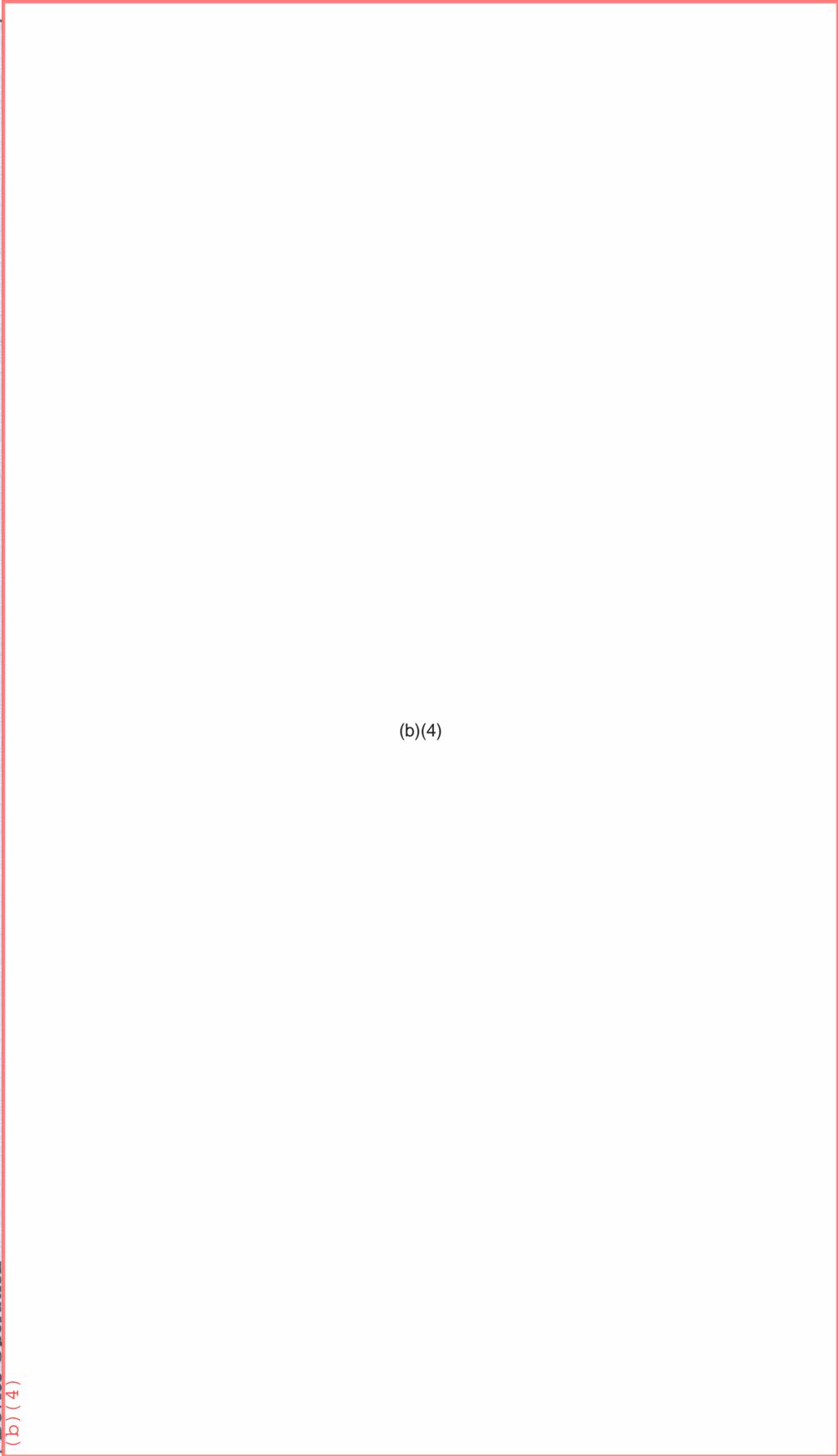
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Table 1: Comparison of System Directions for Use

PL-10691 Rev E

Device Operation

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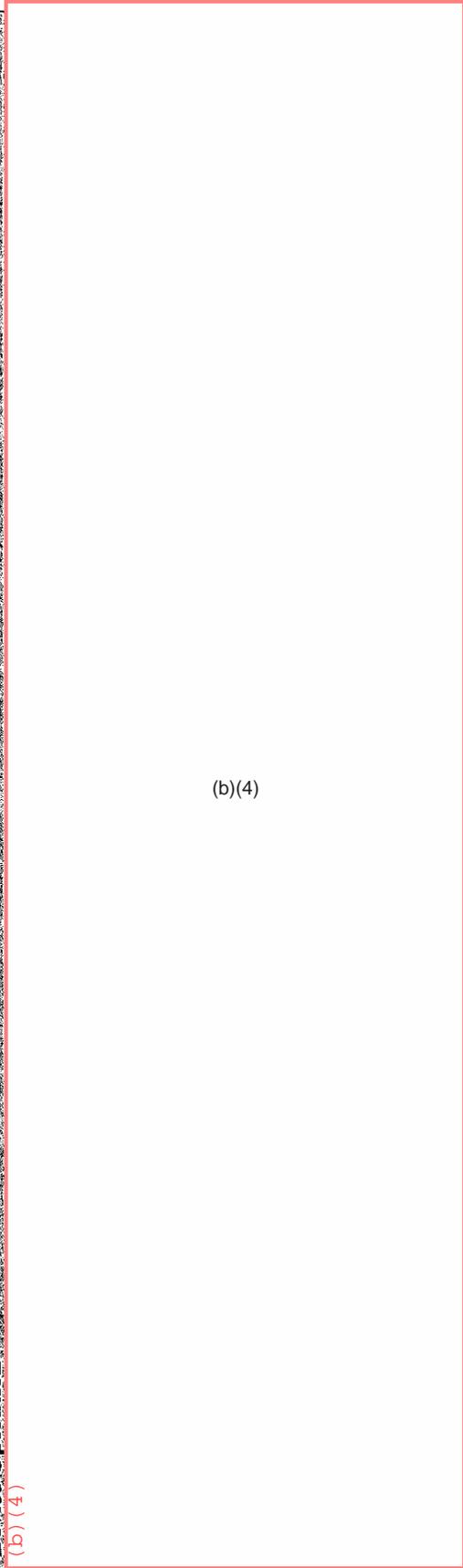
Table 1: Comparison of System Directions for Use

PL-10691 Rev E

PL-12689-01

Device Operation

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Table 2: Comparison of Vacuum Applicator Single Patient Use Sleeve Directions for Use

DR-10862 Rev B

PL-11837 Rev C

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Table 3: Comparison of Belt Applicator Single Patient Use Sleeve Directions for Use

PL-11822 Rev 02

DR-10665 Rev 01

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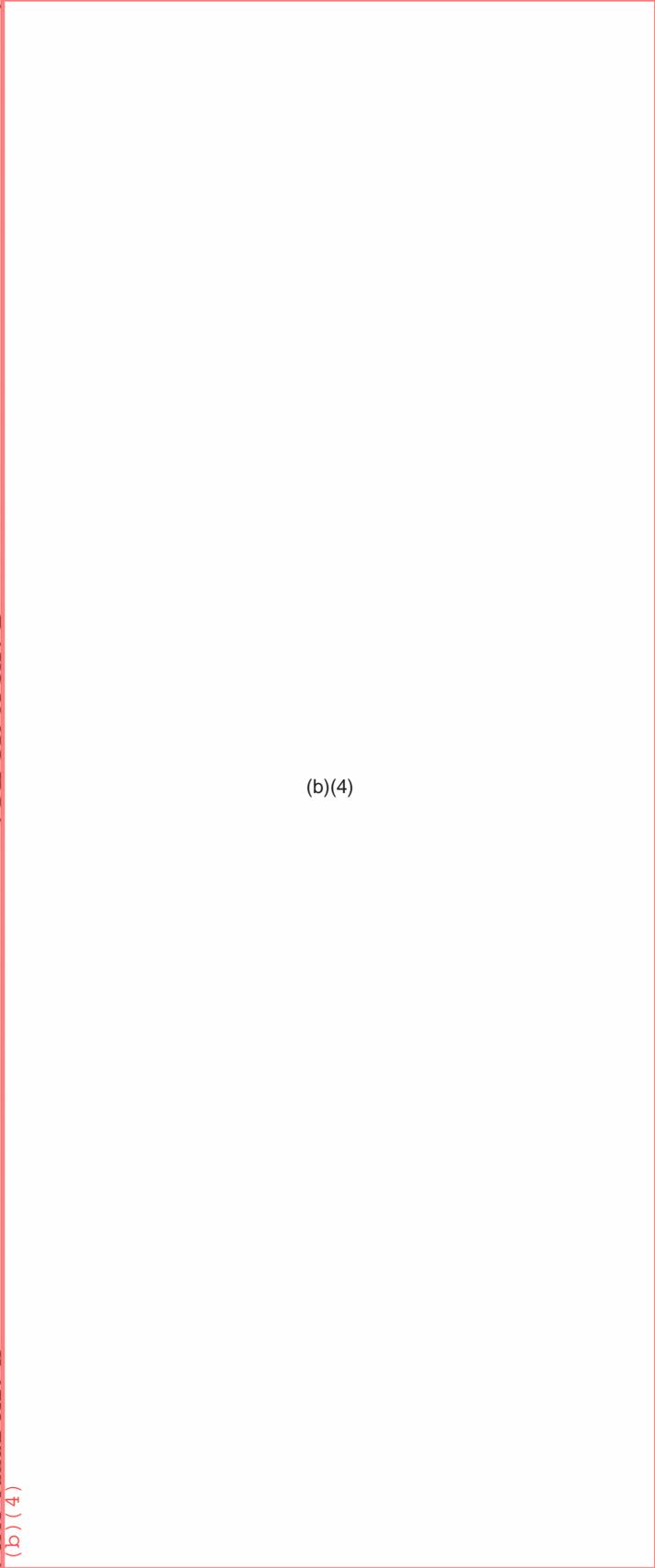
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Table 4: Comparison of Zeltiq Gelpad Directions for Use

DR-10862 Rev B

PL-11940 Rev D

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Attachment 4: Updated User Manuals and Directions for Use



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<table border="1"><tr><td data-bbox="760 1407 816 1461">EC</td><td data-bbox="824 1407 898 1461">REP</td></tr></table>	EC	REP	Authorized Representative Emergo Europe Molenstraat 15 2513 BH, The Hague The Netherlands
EC	REP		

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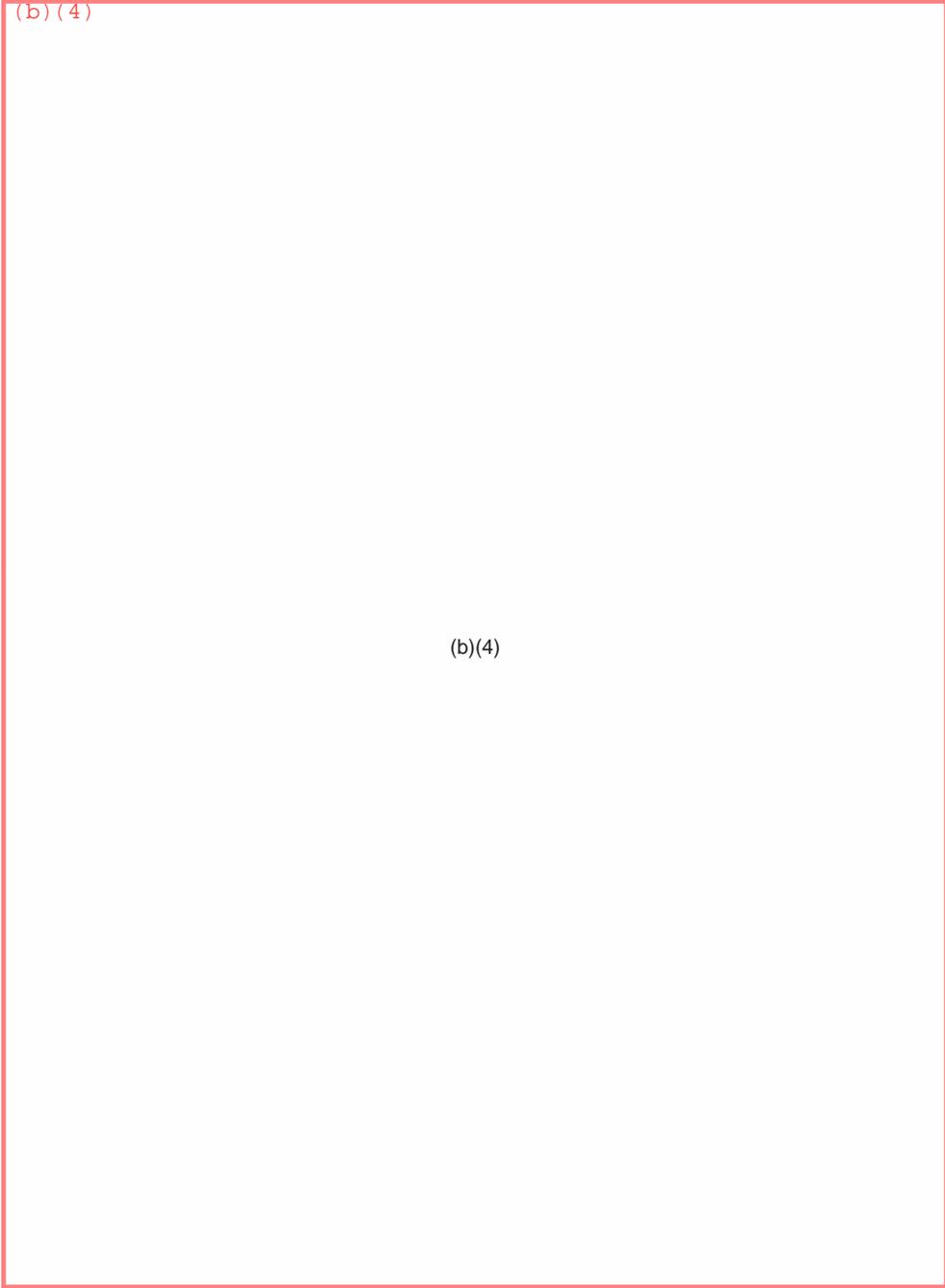
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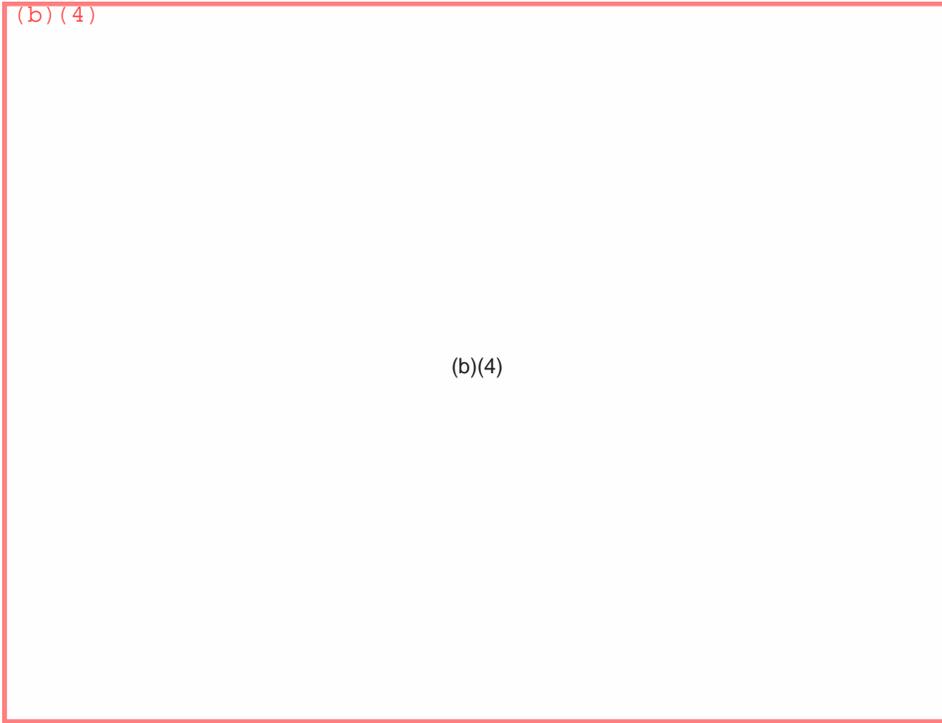


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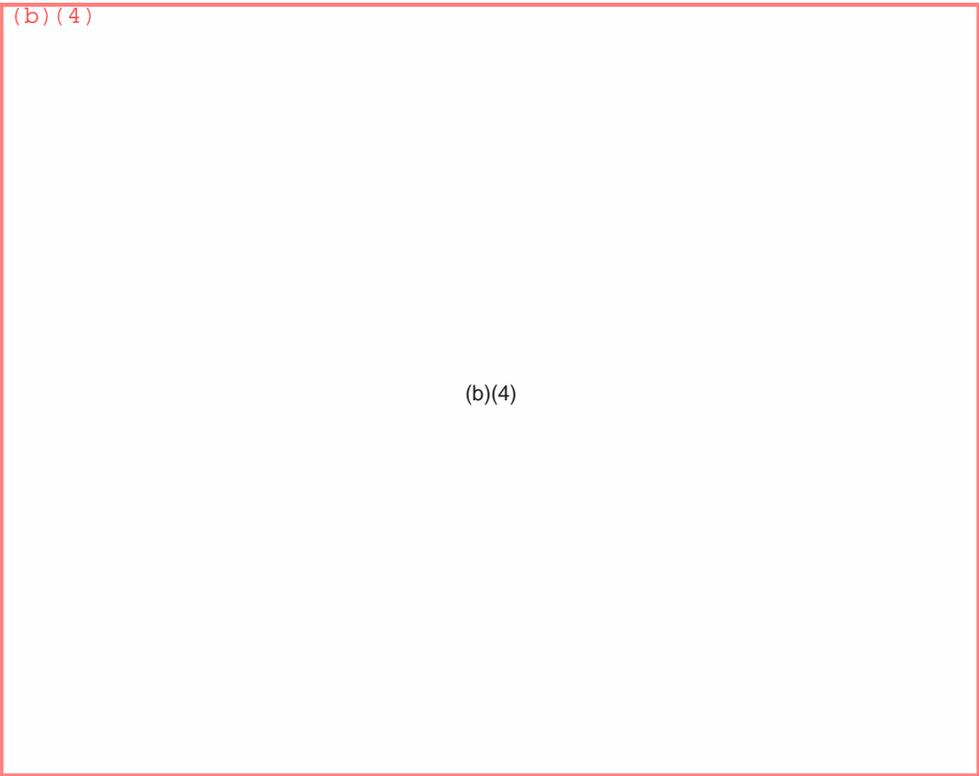
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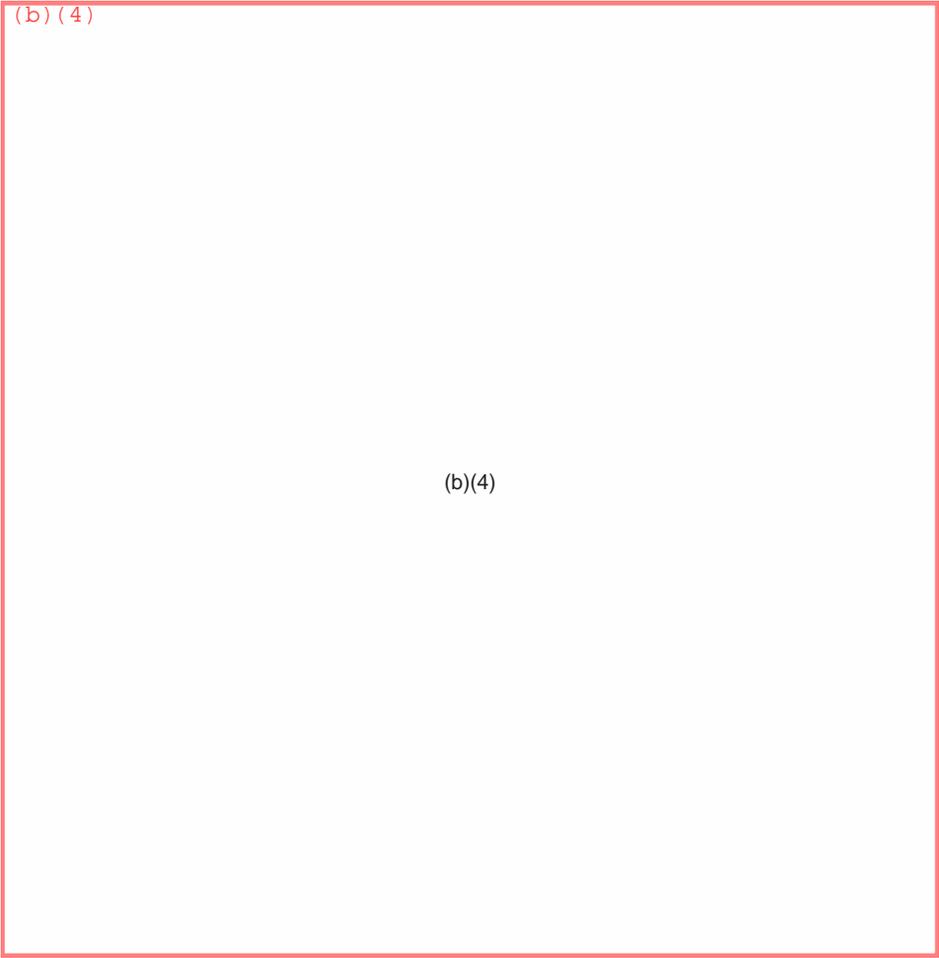
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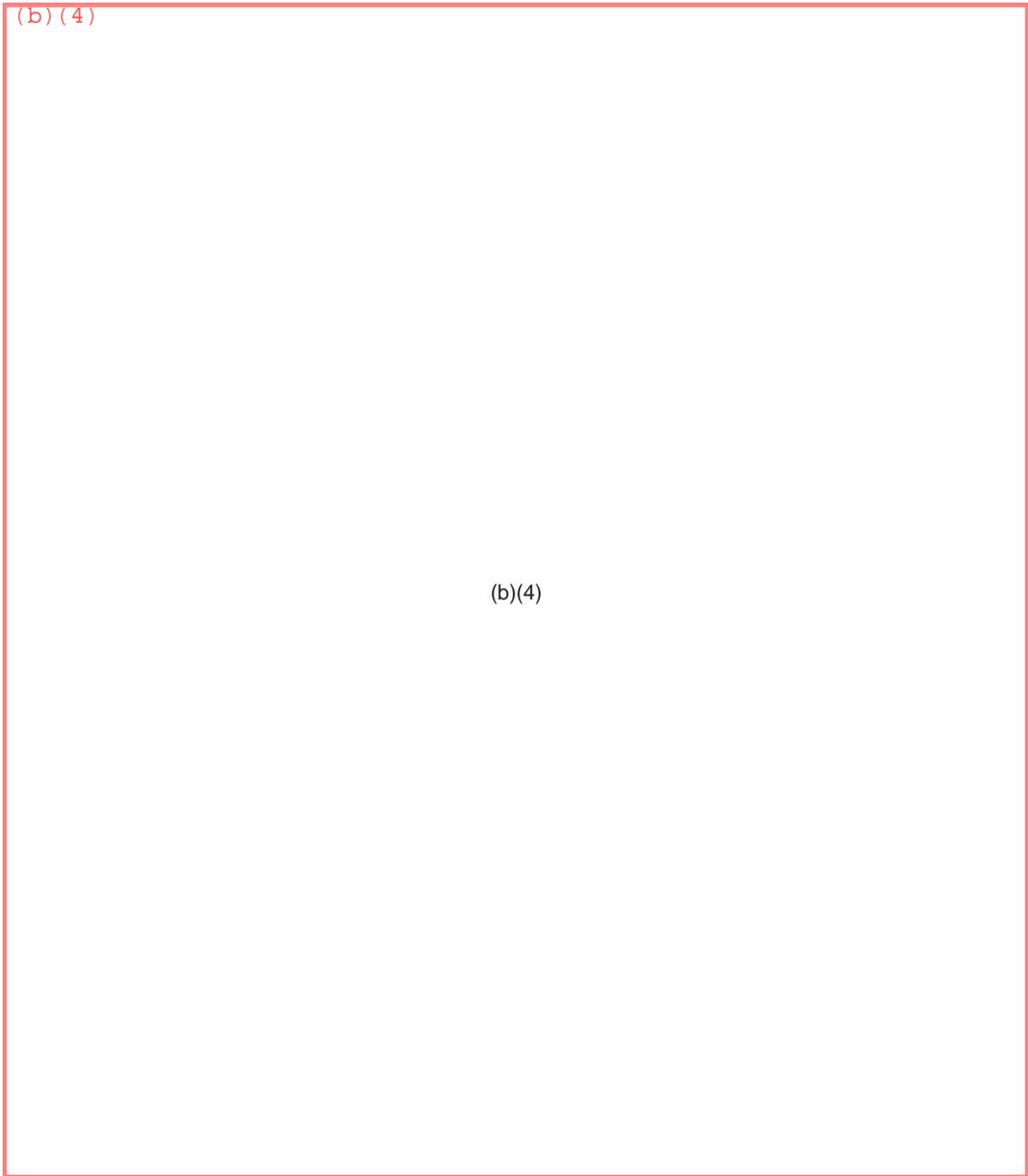
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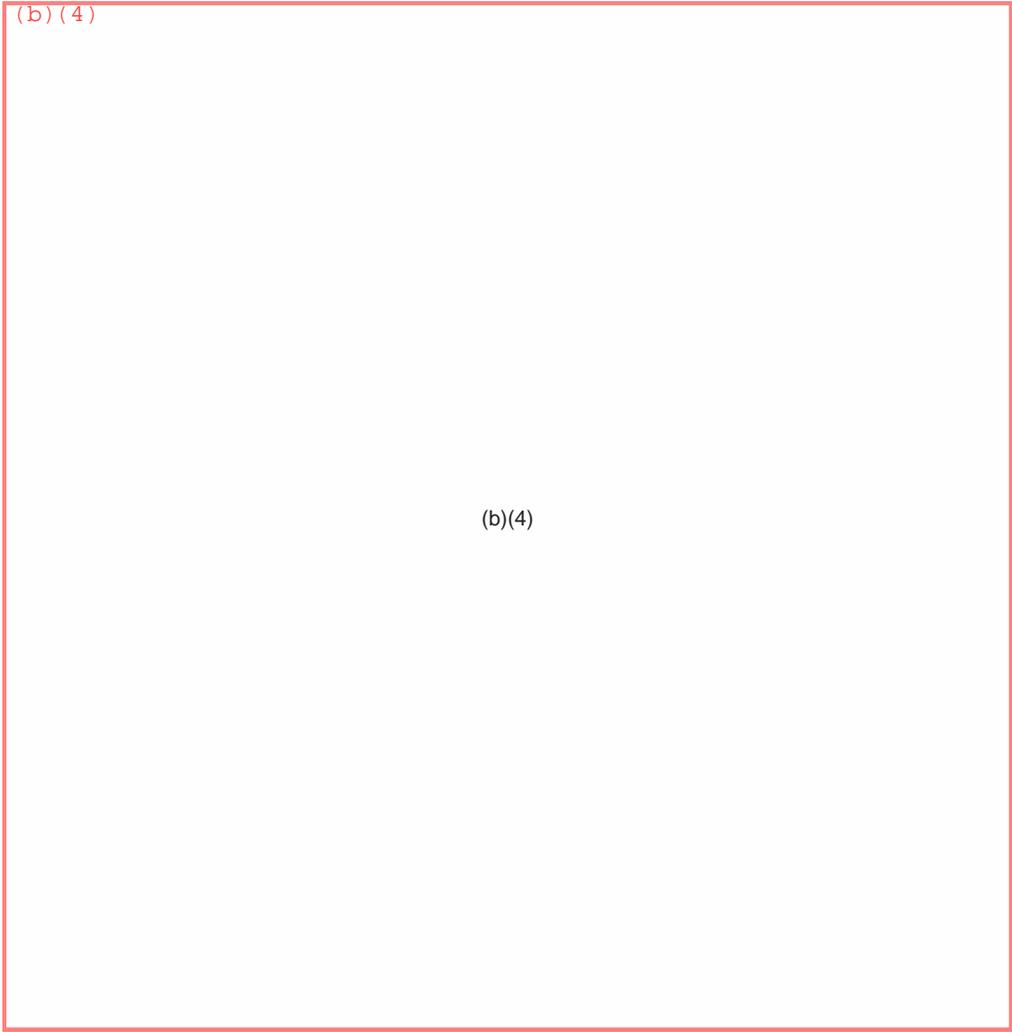
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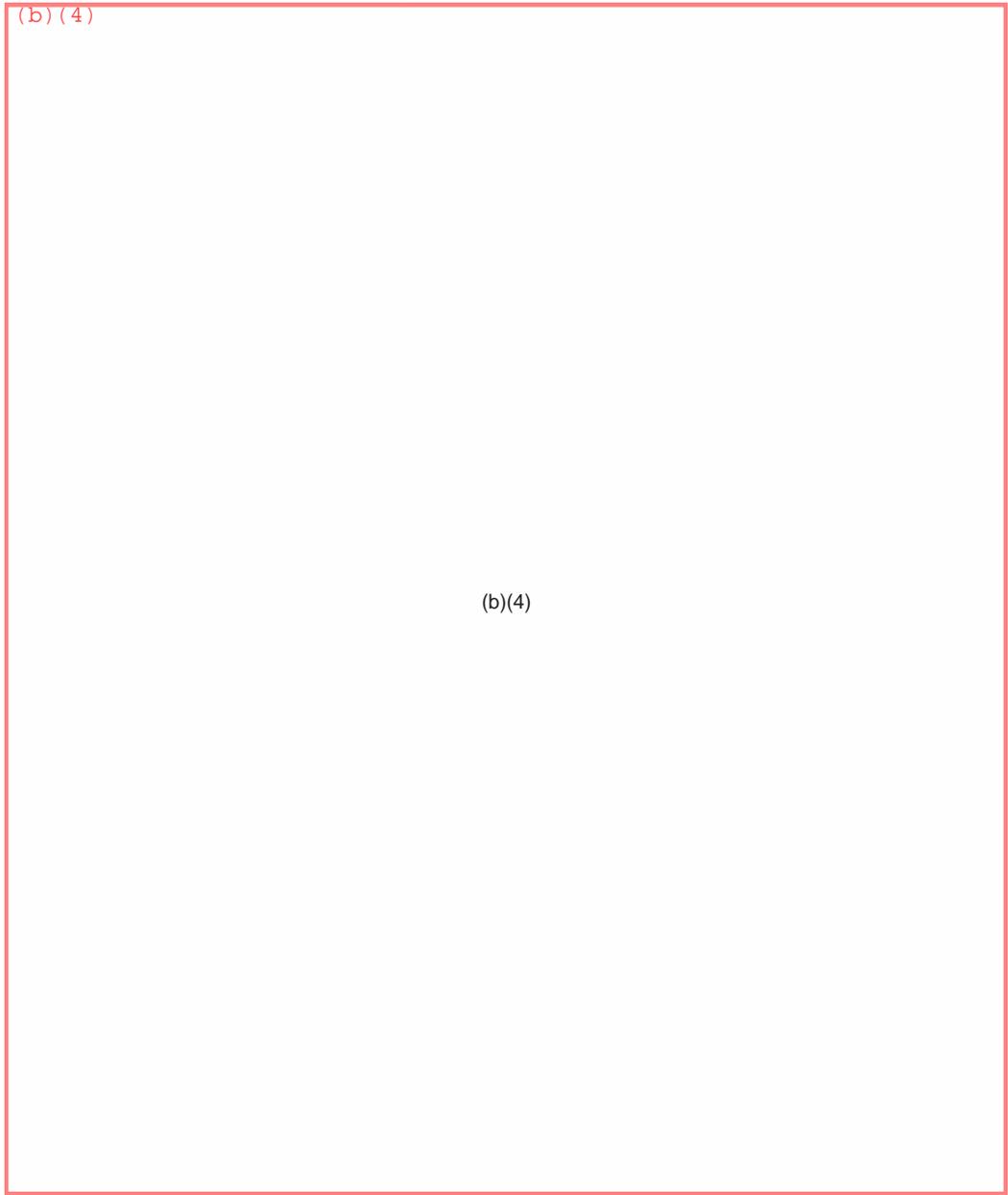
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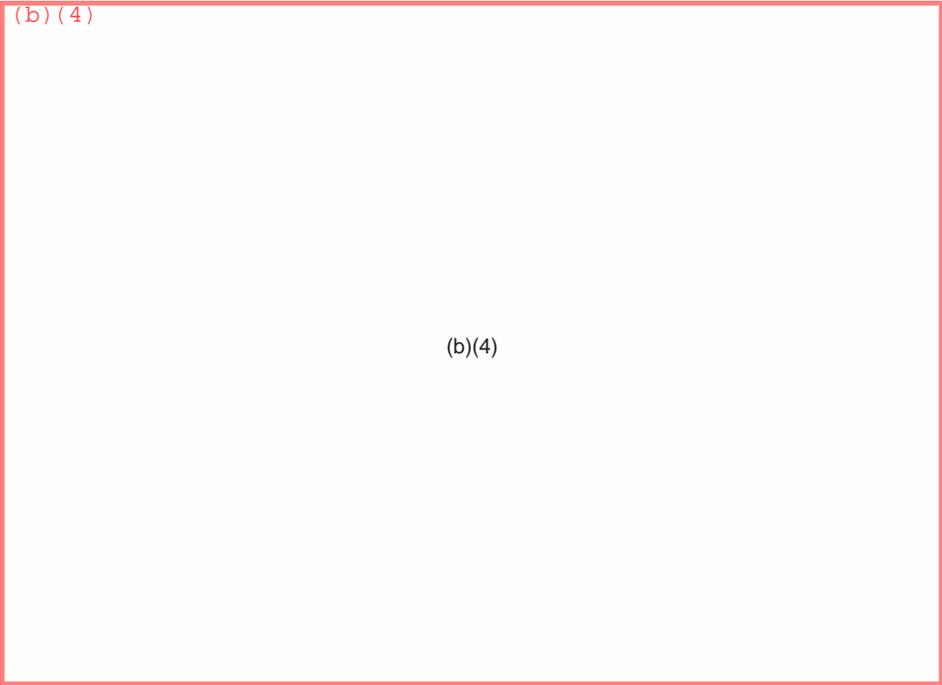
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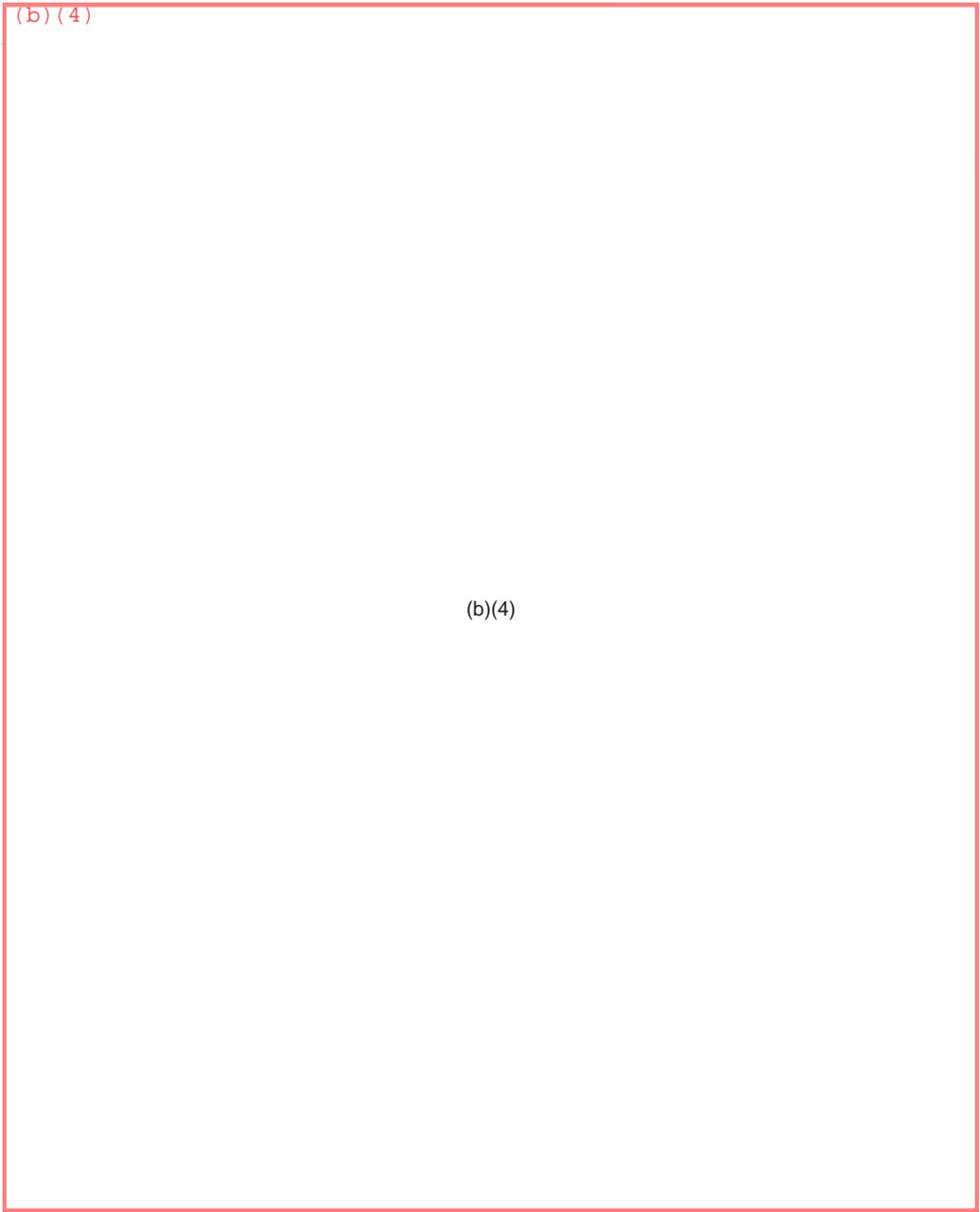
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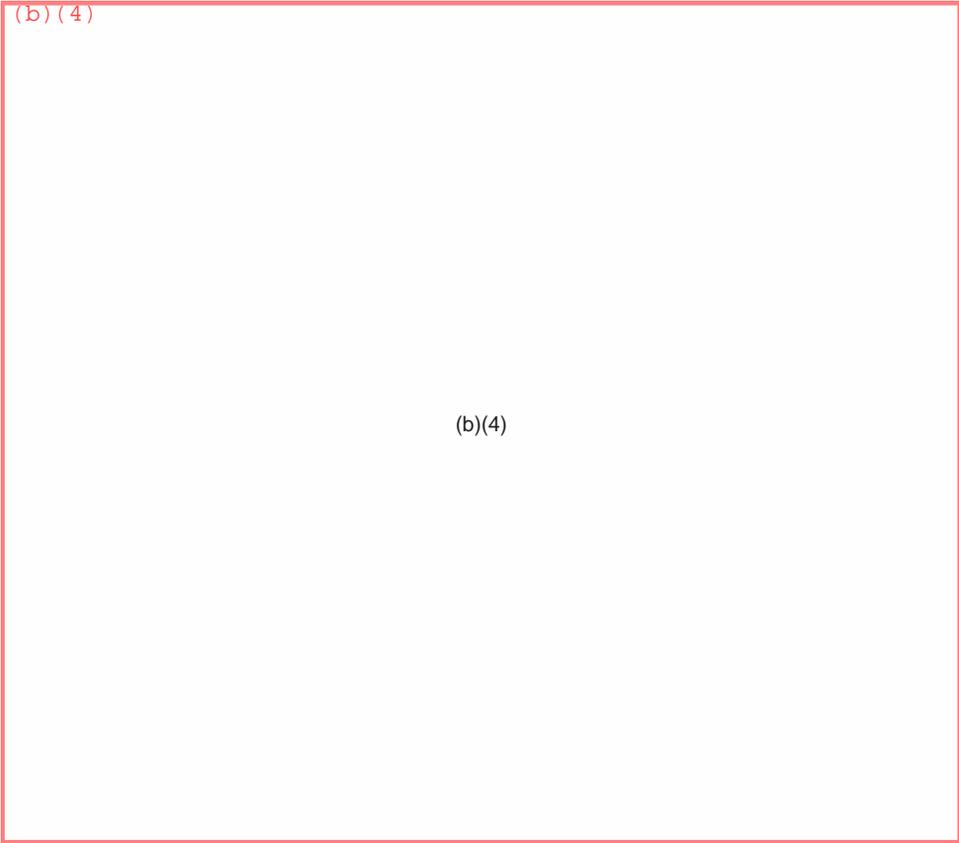
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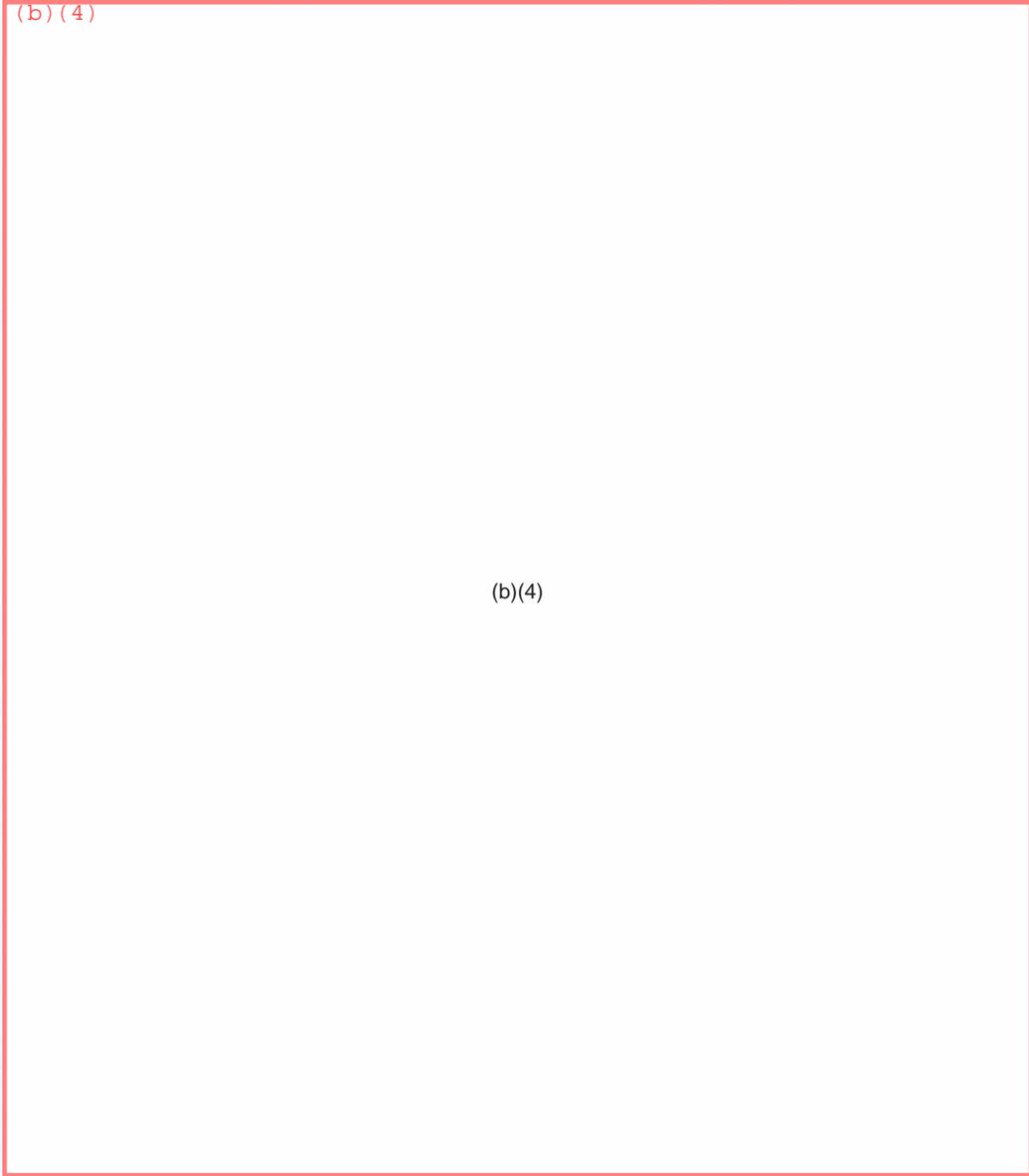
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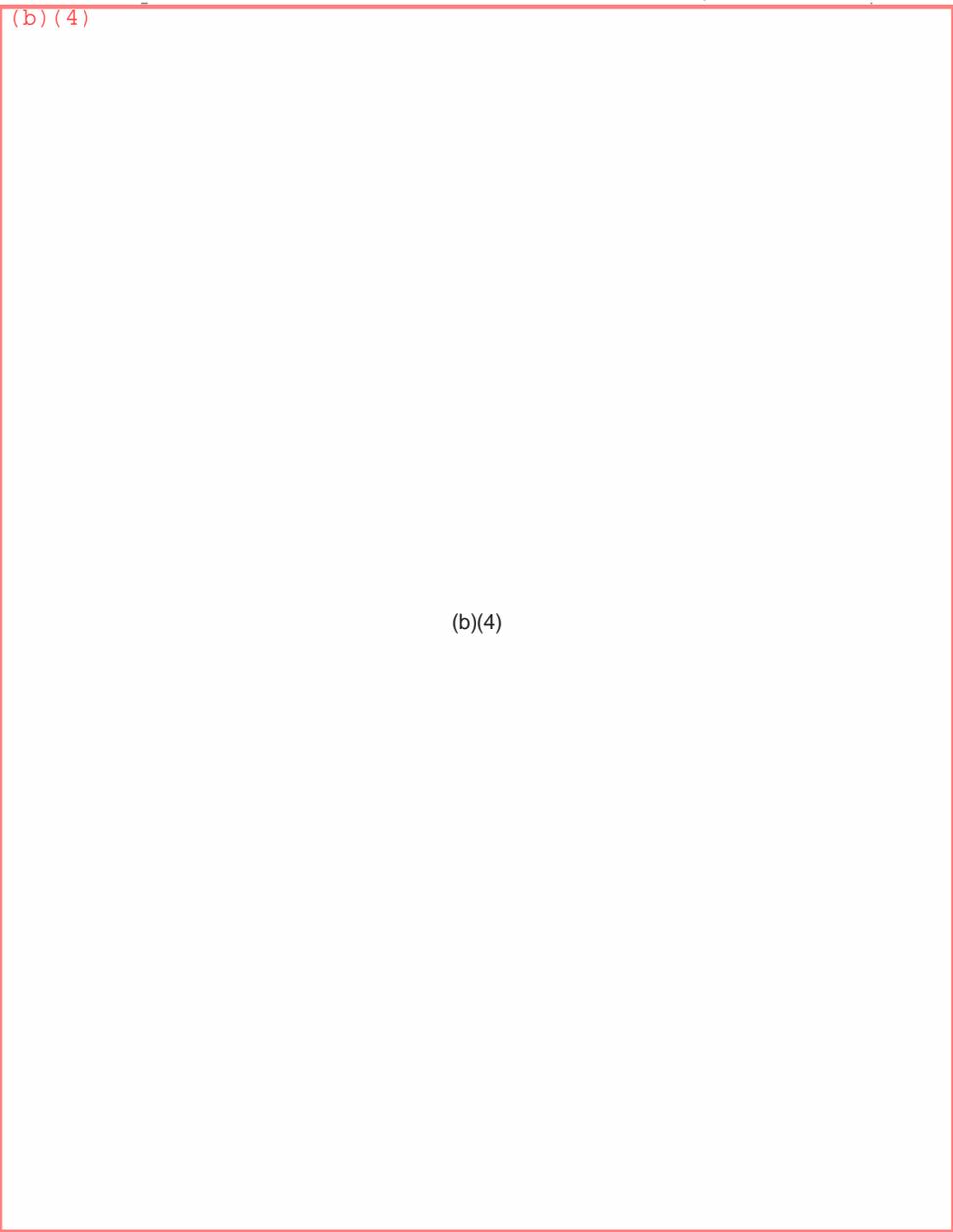
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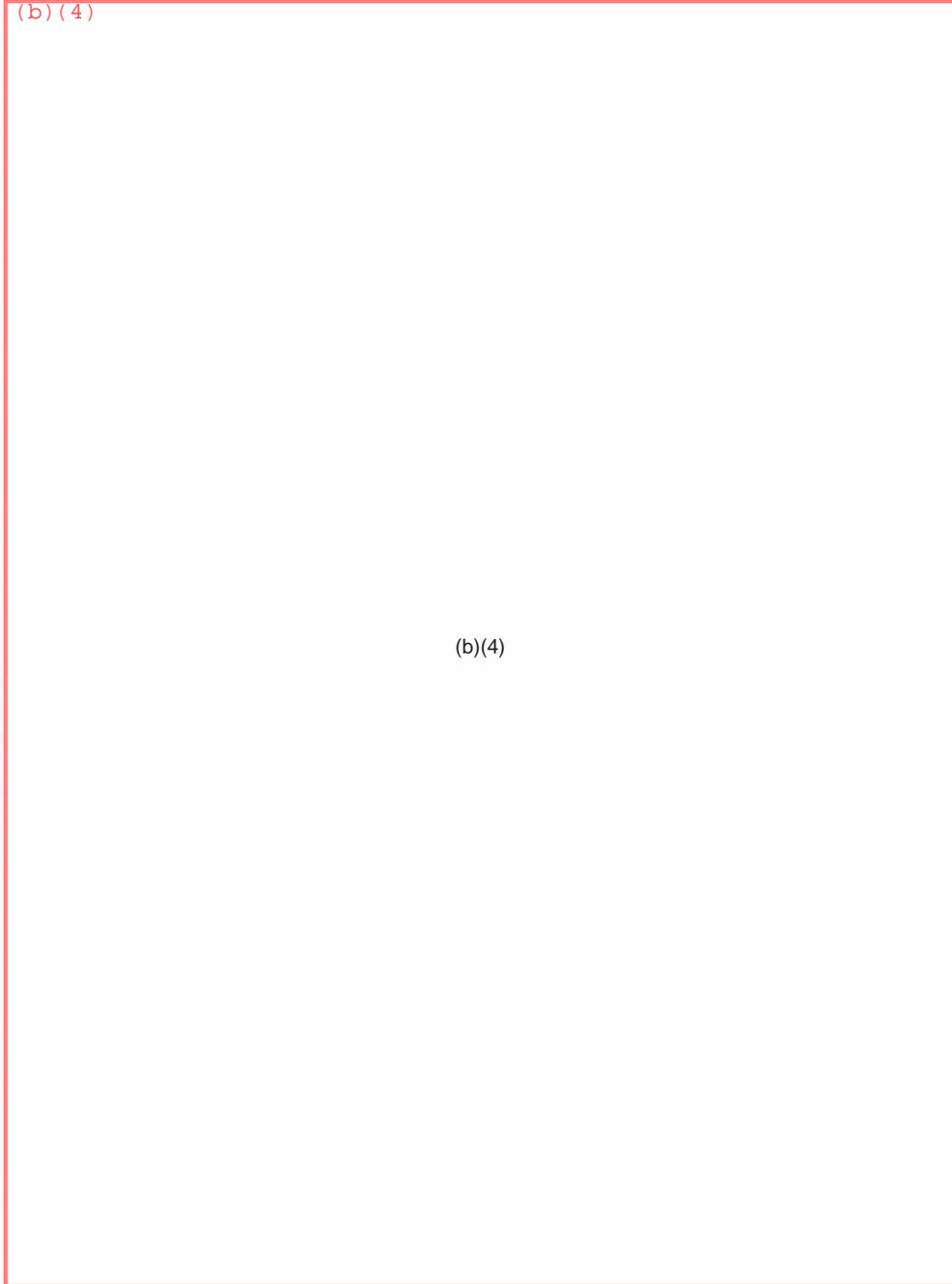
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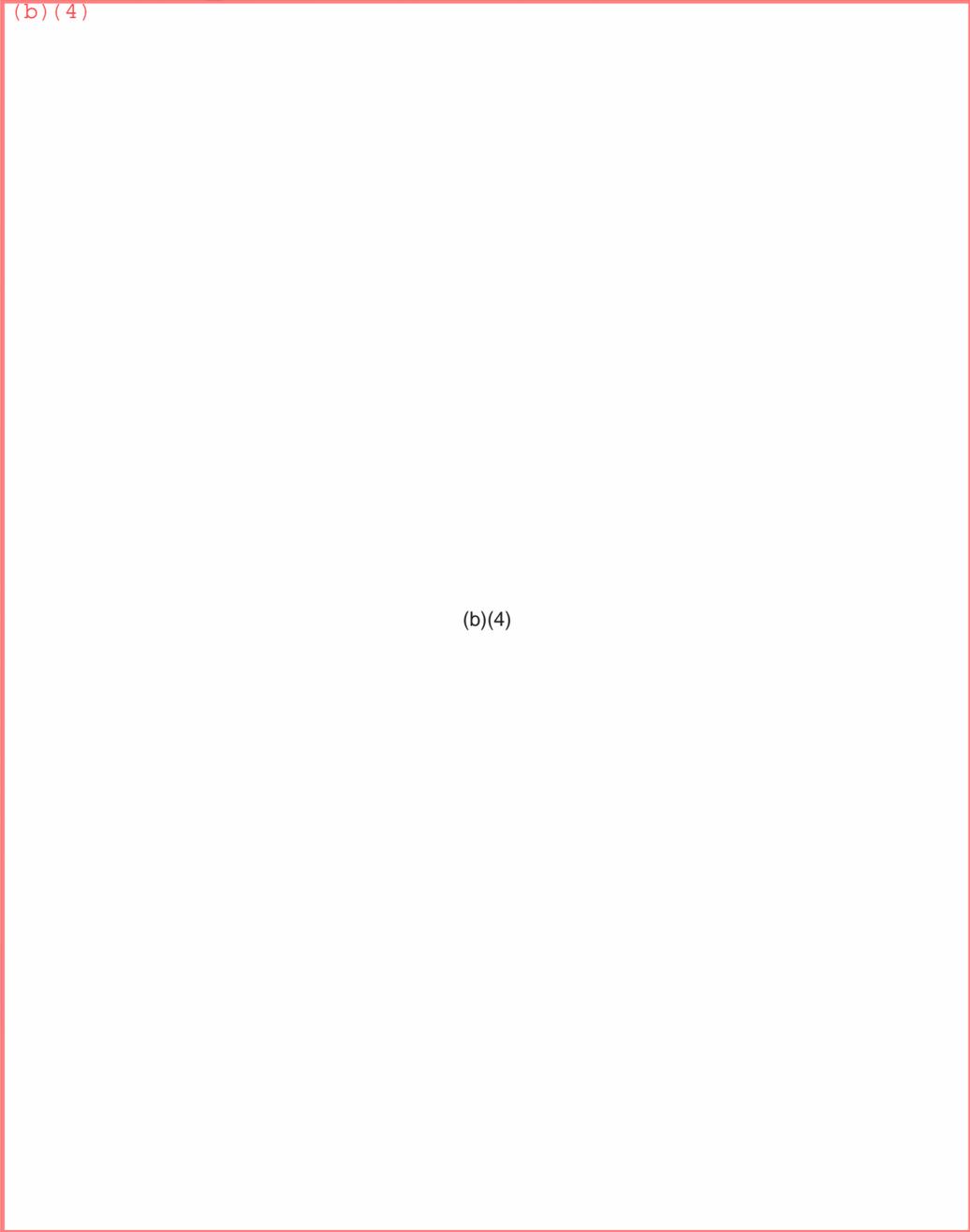
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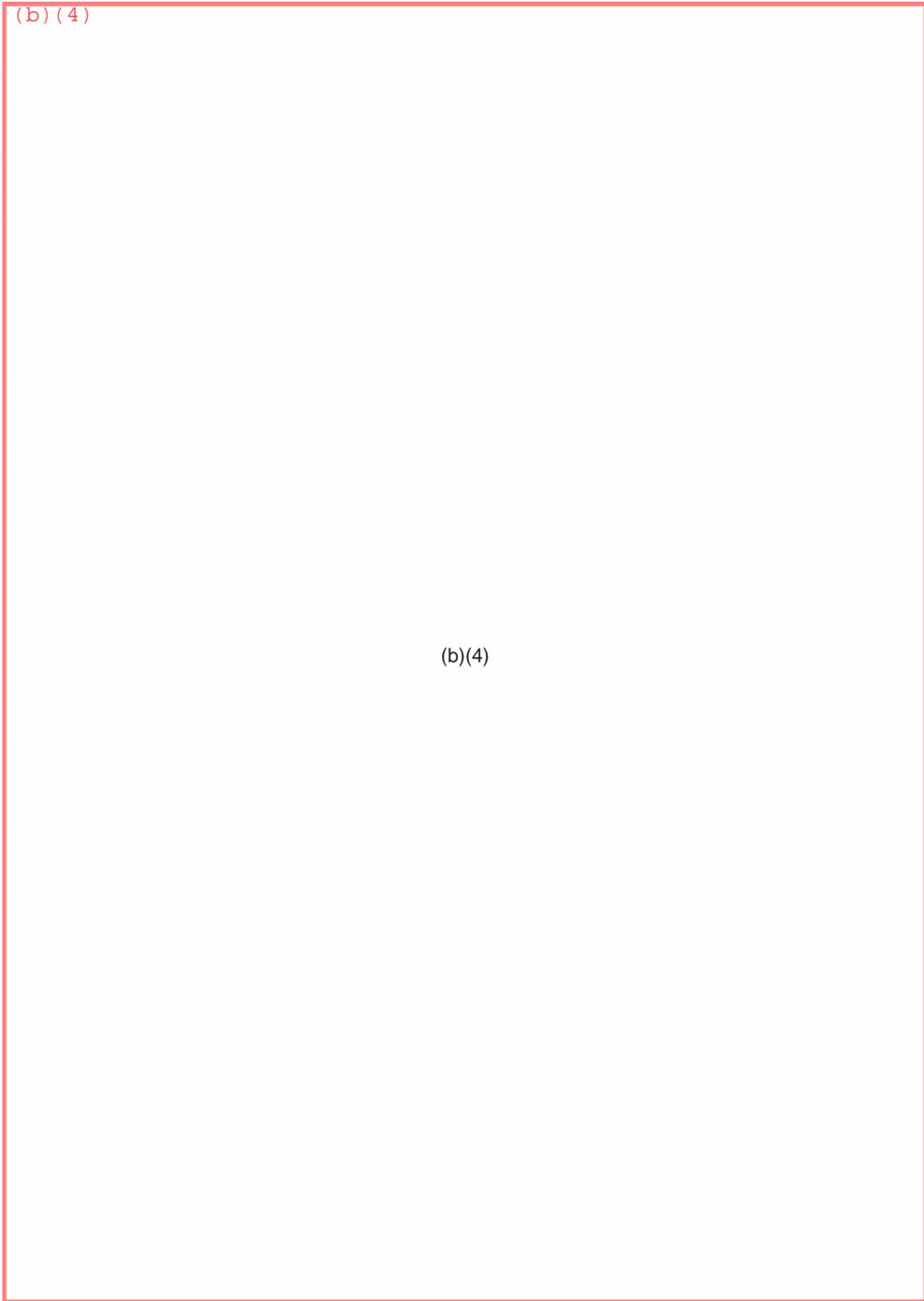


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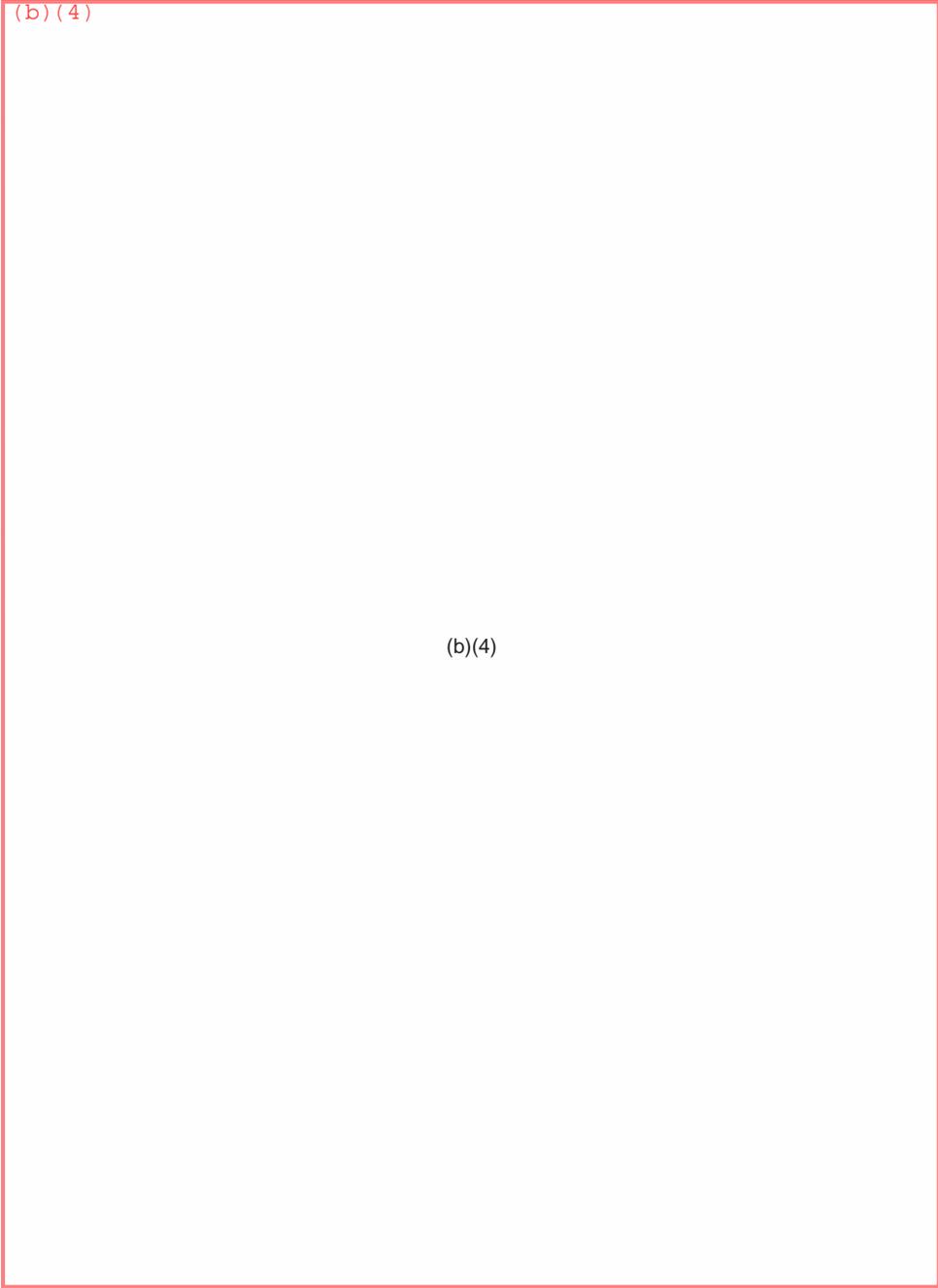
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PLEASANTON, CALIFORNIA 94588
UNITED STATES
ATTN: DONALD V. JOHNSON

510k Number: K090094

Product: ZELTIQ SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

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1090094/52

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission 05/07/2009	User Fee Payment ID Number MD6040736-956733	FDA Submission Document Number (if known) K090094
----------------------------------	------------------------------------------------	------------------------------------------------------

SECTION A TYPE OF SUBMISSION

PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(k) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission? Yes No (If Yes, please complete Section I, Page 5)

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Zeltiq Aesthetics, Inc.	Establishment Registration Number (if known) 3007215625		
Division Name (if applicable)	Phone Number (including area code) (b)(4) (b)(4)		
Street Address 4698 Willow Road	FAX Number (including area code) (b)(4) (b)(4)		
City Pleasanton	State / Province CA	ZIP/Postal Code 94588	Country USA
Contact Name Donald V. Johnson			
Contact Title Vice President, Operations, Regulatory and Quality Affairs	Contact E-mail Address (b)(4) (b)(4)		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name	Phone Number (including area code) ()		
Division Name (if applicable)	FAX Number (including area code) ()		
Street Address	FAX Number (including area code) ()		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

FORM FDA 3514 (9/07)

PAGE 1 OF 5 PAGES

Zeltiq Aesthetics, Inc.
Proprietary and Confidential

K090094, S2 Response

FSC Complaint: (301) 443-1090 EF

1 of 115

1031

23

SECTION D1 REASON FOR APPLICATION - PMA, FDP, OR HDE

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color/Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address

Other Reason (specify):

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Reponse to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

Other Reason (specify):

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
-------------------------------------	-------------------------------------------------------------	-----------------------------------------------

Other Reason (specify):

Additional information requested by FDA via email on 3/4/2009.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness information
 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1		
2		
3		
4		
5		
6		

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Trade or Proprietary or Model Name for This Device	Model Number
1 Zeltiq System	1
2	2
3	3
4	4
5	5

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

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

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section (if applicable)	Device Class
Classification Panel		<input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Indications (from labeling)		

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

FDA Document Number (if known)

SECTION II MANUFACTURING/PACKAGING/STERILIZATION SITES RELATING TO A SUBMISSION

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler		
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) ()		
Street Address			FAX Number (including area code) ()		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
<p>Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:</p> <p style="text-align: center;">Food and Drug Administration CDRH (HFZ-342) 9200 Corporate Blvd. Rockville, MD 20850.</p> <p><i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control</i></p>					



May 8, 2009

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

163
FDA CDRH DMC
MAY 11 2009
Received

RE: Supplement 2 to K090094, Zeltiq System

Dear Dr. Chen:

The letter is in response to a request for additional information presented by FDA in an e-mail dated March 4, 2009. Responses to each of the issues are included with this letter.

(b) (4)
(b)(4)

(b) (4)
(b)(4)

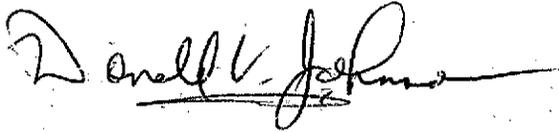
(b) (4) (b)(4)

We would also like to clarify that this change in the language does not impact the risk assessment of this device; in particularly those risks associated with or mitigated by the labeling do not change (b) (4) (b)(4)

We trust that the information is sufficient to continue with review of the submission and appreciate your timely response. If there are any further questions, or if additional information is required, please do not hesitate to contact me at (b)(4) or by email at

(b)(4) (b)(4)

Sincerely,



Donald V. Johnson
Vice President, Operations, Quality and Regulatory Affairs

1) In your response to deficiency#4b in FDA's AI letter dated February 5, 2009, you indicated the use of CIF (the rate of heat extraction), time and message to describe the "profile". However, please note that your device was cleared based on (b) (4) (b)(4)

(b) (4)

(b)(4)

a. Please provide more information regarding the use of CIF index, its definition, and/or calculation formula to demonstrate the use of CIF can indeed be meaningful and representative.

CIF is an index representing the rate of heat flux into or out of tissue opposite the cooling device. A positive CIF describes the rate of heat drawn from the tissue during cooling relative to 37°C. A negative CIF refers to a heat flux into the tissue during heating relative to 37°C.

The use of the CIF is meaningful and representative as a treatment level, therefore, because an increase in the CIF reflects an increase in the rate of cooling and, conversely, a decrease in the CIF reflects a decrease in the rate of cooling.

(b) (4)

(b)(4)

¹ Carslaw, H.S., Jaeger, J.C. (1959). Conduction of heat in solids. New York: Oxford University Press.

(b) (4)

(b)(4)

Table 1. Table of (b) (4) (b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(2)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

(b) (4) (b)(4)

(b) (4) (b)(4) in your profile descriptions (Table 2-2 and Table 2-3, K090094/S1).

(b) (4)

(b)(4)

(b) (4)

(b)(4)

2) In your *AcuCool Vacuum and AcuCool Belt Sleeve Directions for Use*, (b) (4) (b)(4)

(b) (4)

(b)(4)

(b) (4)

(b)(4)

Based on FDA feedback, we propose modifying the statement as follows:

(b) (4)

(b)(4)

(b) (4)

(b)(4)

3) In your revised *Zeltiq System User Manual*, you stated that “The *AcuCool* sleeve has a fixed number of treatment cycles and an overall time limit. When all treatment cycles have been performed or the time limit has been reached, the sleeve is expired and cannot be used again” (page 112 of 150, K090094/S1). However, this information was not included in your *AcuCool Vacuum and AcuCool Belt Sleeve Directions for Use*. Please revise your directions for use and the package label for the *AcuCool Vacuum and AcuCool Belt Sleeve* to include the specific number of treatment cycles and overall time limit included in the subject package and/or device.

The number of treatment cycles and remaining treatment time is determined at the beginning of each treatment cycle. If there is insufficient time or an insufficient number of cycles, the user will not be able to begin treatment. The usage limits will not expire during the middle of a treatment.

The number of applications (e.g., treatment cycles) are on the package labels (see Figure 1) for the vacuum sleeve so that they are available to the user at the time of each procedure. This information is also provided on the user interface as described in the comprehensive User’s Manual (p. 2-7) and reproduced in Figure 2 below. Therefore, we believe that is not necessary to also include the number of treatment cycles and overall time limit in the directions for use specific to the *AcuCool Vacuum and AcuCool Belt Sleeve*.

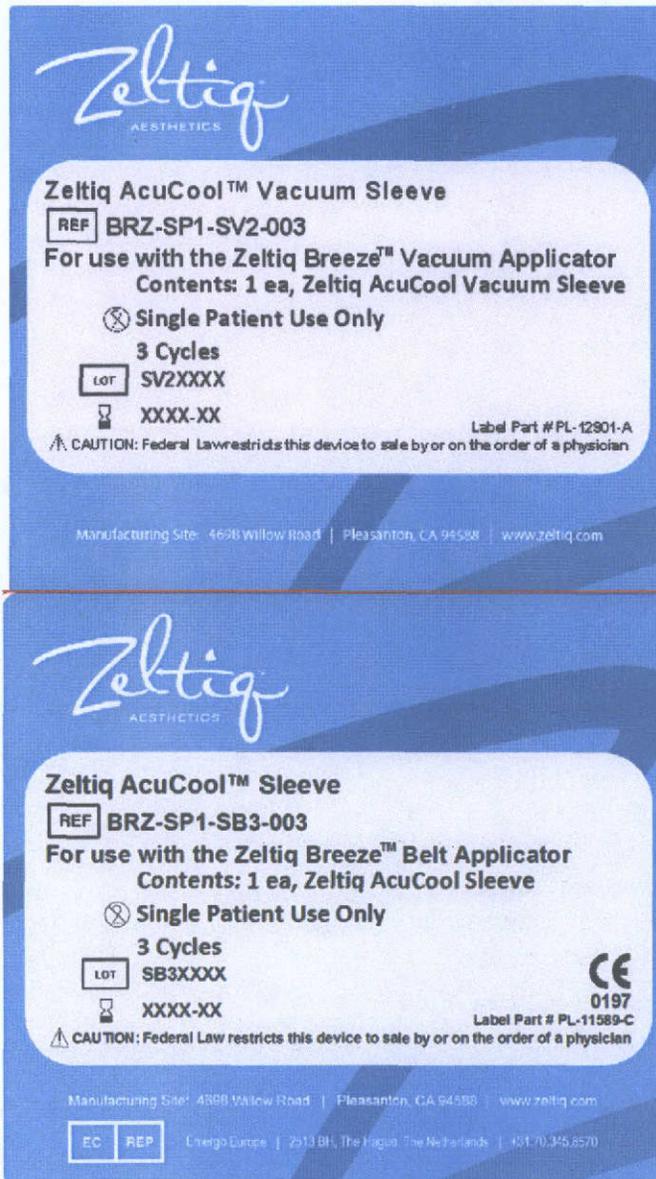


Figure 1: Package Labels

2 After you connect the sleeve, the  mes-

sage is displayed with information on the number of treatment cycles remaining.

If the sleeve is expired, a Recoverable Exception is displayed. Follow the instructions on the screen. ("Control Unit Messages" on page A-1)

Figure 2: Text from Page 2-7 of the User Manual

4) Your predicate device, CLNI Dermal Cooling Device (K080118), (b) (4) (b)(4)

(b) (4)

(b)(4)

5) In your revised user manual, you indicated the use of “modifies pressure/settings for massage” in your control unit display (page 78 of 150, K090094/S1). Please note that your device was cleared based on specific vacuum pressure that was presented to the Agency. (b)(4)

(b)(4)

(b)(4)

a. Please provide more information regarding the use of “modifies pressure settings for massage” in your control unit display, its definition, and/or calculation formula to demonstrate the use of “modifies pressure settings for massage” is meaningful and representative.

The language “modifies pressure setting for massage” is intended as a label to identify the function of that soft key just as the knob used to adjust the pressure for the predicate device was identified in the user labeling. (b)(4) (b)(4)

(b)(4) (b)(4)

(b)(4) (b)(4)

(b)(4) (b)(4)

(b)(4) (b)(4) This range of values holds for both the Vacuum settings described on page 2-14, as well as the Max and Min massage vacuum pressure settings described on page 2-15. During the massage cycle, the massage alternates between the Max and Min pressure settings to provide the massage effect.

b. Please provide your recommended modified massage pressure settings for the user together with the actual vacuum pressure in “in. Hg”.

A specific recommended massage pressure is not included in the Zeltiq System labeling, which is consistent with that of the predicate device. The labeling for the predicate device, as submitted in K080118, included the following statement regarding massage:

“If massage is used, the massage pressure may be adjusted with the smaller knob during the massage segment of treatment.”

Pages 2-14 to 2-17 of the User Manual for the device that is the subject of this submission, K090094, describe how to set both the vacuum pressure and the massage pressure settings. In particular, it states:

- 1) Page 2-14: “Vacuum pressure: press - and + buttons to decrease and increase vacuum pressure.” Hence, as the values increase over the (b)(4) the vacuum pressure increases.
- 2) Page 2-15: “Press the down and up arrows to decrease and increase the Max and Min pressure for massage.” As before, as the values increase over the (b)(4) the

vacuum pressure increases. The Max value is the maximum massage pressure during a cycle and the Min value is the minimum massage pressure during a cycle.

- 3) Page 2-17: "Press the Max and Min arrow buttons during the procedure if needed to ensure adequate vacuum pressure for massage and to enhance patient comfort."

Zeltiq also proposes to include the following statement about the value displayed on the user interface "Profile and Vacuum" and "Vacuum Settings Screens". This change is incorporated in the attached draft change to the User's Manual.

Note: The default setting for the Zeltiq System vacuum applicator, with or without massage, will be set to (b)(4) which is the same value that is recommended upon initiation of the vacuum for the predicate device. The screen shots in the User Manual will be changed to reflect this default value. (The screen shots in the User Manual previously submitted show a (b)(4) (b)(4))

The revised User Manual has been provided in Attachment 1.

c. Please provide data to support that your recommended massage pressure settings will be safe for the patient.

As stated previously, there are no recommended massage pressure settings for the device. It is important to note, however, that the maximum pressure setting is equivalent (b)(4) which is less than the maximum pressure setting of the predicate (b)(4). Therefore, although we respect FDA's concern about potential safety issues, we do not feel it is necessary to provide additional safety data for the Zeltiq System with respect to the pressure settings for the following reasons:

- the maximum pressure setting is less than that of the predicate;
- there is no change to the vacuum pump or function; and
- there is no change to the risk assessment with respect to the massage function.

6) Your predicate device, CLNI Dermal Cooling Device (K080118), was cleared with the following precaution: (b) (4) (b)(4)

(b) (4)
(b)(4)
(b) (4) (b)(4)

a. Please provide detailed information of this modification.

The intent of this change was to provide a more general recommendation about the use of excessive vacuum pressure as the potential of bruising is not specific to a certain vacuum pressure (b) (4) (b)(4) but dependent on many variables associated with the patient. Bruising, and the potential for discomfort due to the vacuum, may occur at a higher or lower pressure than (b) (4) (b)(4) regardless of the duration.

b. Please describe your safety limit of the modified vacuum pressure setting.

As previously mentioned, the maximum settable vacuum pressure for this device is (b) (4) (b)(4) which is less than the maximum vacuum pressure of (b) (4) (b)(4) for the predicate. (See K080118: Hazard Analysis, Current Design Mitigations, page 130 of 454). This limit is controlled by the system software as defined by the design documentation in Attachment 2, DR-11071, COM1 Software Requirements Specification. The key software requirement implementing these safety limits is

- SRS:122 The software shall limit the vacuum settings to the range from (b) (4) (b)(4)

c. Please provide validation that this modification has been implemented properly. Please note that the risk analysis you provided in this supplement (Attachment 2, K090094/S1) indicates that the maximum settable pressure from the vacuum pump shall be less than (b) (4) (b)(4)

Validation of the software-controlled, maximum settable vacuum pressure setting of (b) (4) (b)(4) was completed as part of the software verification and validation for the Zeltiq System. This has been documented in Attachment 4, TR-177, COM1 SW Verification Results, SW Release 03.6 Report. The highlighted step 38 demonstrates that the maximum settable vacuum pressure (b) (4) (b)(4) thus meeting the requirement from the risk analysis that states that the maximum settable pressure shall be less than (b) (4) (b)(4)

7) Your revised Zeltiq System User Manual include following exculpatory languages (page 70 of 150, K090094/S1):

- *“Zeltiq Aesthetics makes no warranty, expressed or implied, with regard to the content of its user documentation including but not limited to warranty of fitness for a particular purpose” and*
- *“Zeltiq Aesthetics shall not be liable for errors contained in its user documentation or for damages that might arise in connection with the furnishing, performance, or use of this material”.*

This is not acceptable. Please remove any exculpatory language that is intended to release the sponsor from liability for negligence.

The language is being removed as requested as can be seen in the revised User Manual in Attachment 1.

Attachment 1: PL-12689, Zeltiq System User Manual



Zeltiq System User Manual

Zeltiq Aesthetics, Inc. Proprietary and Confidential. Do not distribute.

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U.S.A.
(925) 474-2500
www.zeltiq.com



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2513 BH, The Hague
The Netherlands
Tel: (+31) 70 345 8570
Fax: (+31) 70 346 7299



Zeltiq Customer Service
Worldwide: (+1) 925-474-8160
U.S.A.: 1-888-935-8471
(1-888-ZELTIQ1)

PL-12689-02

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K090094, S2 Response

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Intellectual Property

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ZELTIQ AESTHETICS, ZELTIQ, ZELTIQ BREEZE, Zeltiq Breeze logos, the Zeltiq Logo, ACUCOOL, CRYOLIPOLYSIS, and "More Science. Less Fat." are trademarks of Zeltiq Aesthetics, Inc. in the United States of America and other countries. All rights reserved.

The products described in this document may be covered by one or more of the following U.S. Patents: 7,367,341, 6,032,075, and D568,258. Other patents and patent applications pending worldwide.

Intended Use

The Zeltiq™ System (system) is intended for use as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments. Alternative uses include:

- Skin cooling as a local anesthetic for procedures that induce minor local discomfort.
- Localized thermal therapy (hot or cold) to minimize pain for post traumatic and/or post surgical pain and to temporarily relieve minor aches and pains and muscle spasms.
- The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm, for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.



CAUTION: In the United States of America, Federal law restricts this device to sale by or on the order of a physician.

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Contraindications

Localized skin cooling is contraindicated in patients who have:

- Cryoglobulinemia
- Paroxysmal cold hemoglobinuria

Warnings

Caution should be taken when localized cooling or heating is performed under the following conditions, the effects of which have not been studied:

- Cold urticaria
- Areas of impaired peripheral circulation
- Raynaud's disease
- Pregnancy
- Scar tissue or extensive skin conditions such as eczema or dermatitis at the area of intended treatment
- Impaired skin sensation
- Open or infected wounds
- Areas of recent bleeding or hemorrhage (heating)

The effect of performing Zeltiq procedures directly over active implanted devices in patients, such as pacemakers and defibrillators, is not known.



WARNING: The effects of simultaneous use of massage and cold with the Zeltiq System have not been established, and such simultaneous use should be avoided.



WARNING: Before using the Zeltiq System, read and understand the User Documentation set. See User Documentation on page vi.

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Cautions

The system is intended for use by a trained physician or a physician-designated medical professional such as a nurse or aesthetician.

If the operator observes a potential safety issue or operational abnormality during use, the procedure should be terminated and Zeltiq Customer Service should be contacted promptly at 1-888-935-8471 (1-888-ZELTIQ1).

The use of other equipment and supplies with the Zeltiq System has not been tested and may cause unexpected results.

About the Zeltiq System

The Zeltiq System is comprised of the Zeltiq Breeze™ Control Unit (control unit), a Zeltiq Breeze applicator, an AcuCool™ sleeve (sleeve), and a Zeltiq Gelpad (Gelpad). The Gelpad provides thermal coupling at the interface between the sleeve and the patient's skin. Sensors in the sleeve monitor the skin surface, providing feedback that controls the heat flux.

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System Symbols

The following symbols are used on the components of the system and on its supplies and packaging.

	Do not reuse (Gelpad) Single-patient use only (Acu-Cool™ sleeve)		Type BF -- Floating patient applied parts. Not for use in conjunction with defibrillators.
	Manufacturer		Date of Manufacture
	Authorized European Representative		Use by Date
	Equipotential contact		Potential for Electromagnetic Interference
	Caution		Consult Documentation
	On (Power)		Off (Power)
	Treatment cycle status panel (touch pad)		Vacuum Panel (touch pad)
	Special disposal methods are required for this electrical device		CE marking

Table 1: System Symbols

For information on symbols and indicators that are displayed on the screen, see "Information on the Screen" on page 1-4.

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User Documentation

Zeltiq Aesthetics provides comprehensive user documentation as described below.



NOTE: All depictions in Zeltiq user documentation are sample images. Your hardware and information on the system screen may differ from those depicted in the documentation.

Zeltiq System User Manual

The *Zeltiq System User Manual* provides detailed information on the components of the Zeltiq System, performing Zeltiq procedures with the Zeltiq Breeze Belt Applicator and Zeltiq Breeze Vacuum Applicator, troubleshooting, cleaning, and maintenance.

Zeltiq AcuCool Vacuum Sleeve Directions for Use

The *Zeltiq AcuCool Vacuum Sleeve Directions for Use* provides detailed information on installing the AcuCool Vacuum Sleeve on the Zeltiq Breeze Vacuum Applicator. This document is included in each shipment of vacuum sleeves.

Zeltiq AcuCool Belt Sleeve Directions for Use

The *Zeltiq AcuCool Belt Sleeve Directions for Use* provides detailed information on installing the AcuCool Belt Sleeve on the Zeltiq Breeze Belt Applicator. This document is included in each shipment of belt sleeves.

Zeltiq Gelpad Directions for Use

The *Zeltiq Gelpad Directions for Use* provides detailed information on the safety features, requirements, and use of the Zeltiq Gelpad. This document is included in each shipment of Gelpads.

Zeltiq Aesthetics reserves the right to modify the content of the user documentation at any time. Retain the most current user documentation and always review it prior to using an applicator, sleeve, or Gelpad.

Conventions in User Documentation

Icon	Table Name	Description
	Note	Additional information that is not associated with risk.
	Caution	Use or misuse of the device is associated with risk of minor temporary injury and damage to equipment.
	Warning	Use or misuse of the device is associated with risk of serious and/or permanent injury and death.

Table 2: Symbols in User Documentation

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Chapter 1: System Overview

This chapter describes the Zeltiq Procedure and the Zeltiq System (system).

Contents

- “Zeltiq Breeze Control Unit” on page 1-1.
- “Zeltiq Breeze Applicators” on page 1-10
- “Pager” on page 1-11
- “Call Button” on page 1-16
- “Supplies” on page 1-17

See Also

- “Zeltiq Procedures” on page 2-1

Zeltiq Breeze Control Unit

The Zeltiq Breeze Control Unit (control unit) is a portable device that is used to start, stop, and monitor Zeltiq procedures.

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Control Unit - Front View

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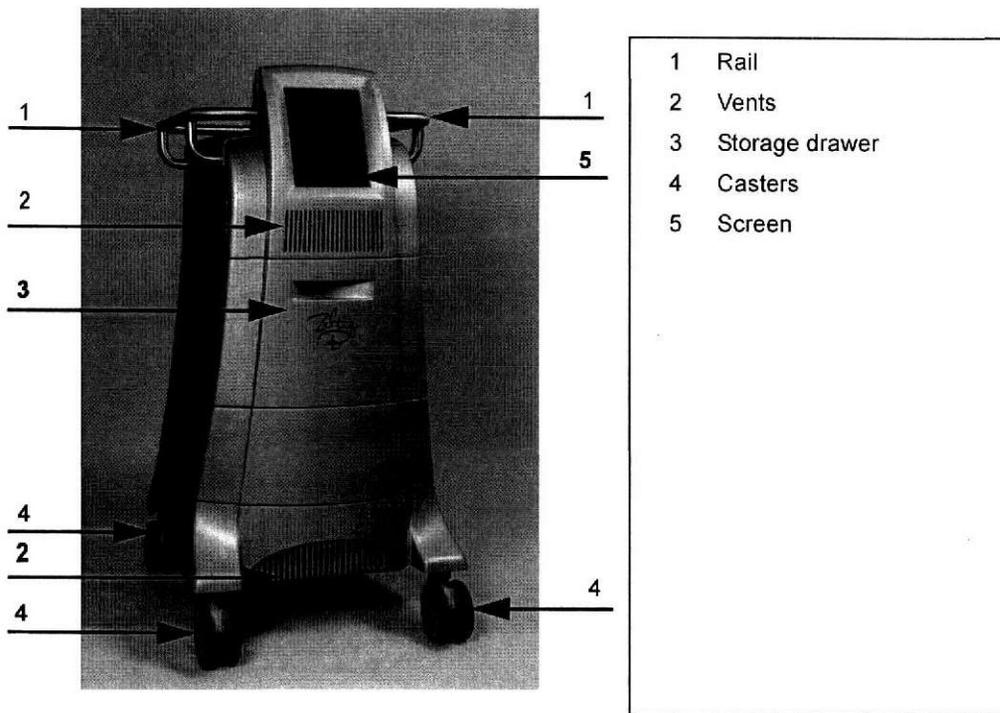


Figure 1-1: Control Unit - Front View

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Rail

When the applicator is resting on top of the control unit, the rail helps keep the applicator in place. In addition, the rail is used as a handle to move the system.

"Moving the Control Unit" on page 1-8.

Vents

Vents provide airflow that reduces heat build-up inside the control unit. Ensure all vents are free from obstructions when the control unit is in operation.

Drawer

The drawer provides storage space for an applicator, Gelpads, user documentation, alcohol wipes, and other frequent-use items.

Casters

The control unit has four casters that swivel. Each caster has a brake. Always engage the brakes on all four casters before you use the control unit.

To engage and release the brakes:

- 1 Press down on the brake lever with the toe of your shoe.
- 2 Pull up on the brake lever with the toe of your shoe.

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Information on the Screen

The screen on the control unit displays control buttons and status information.

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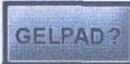
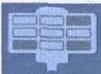
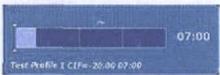
Button	Description	Button	
	Press the Gelpad? button to indicate that a new Gelpad is on the application site.		Indicates the Gelpad button was pressed.
	Goes to the next screen		Goes to the previous screen
	Caution		Displays the list of profiles
	Start Cycle		Cancels the activity in progress
	Vacuum Status: Press to turn vacuum on		Vacuum Status: Press to turn vacuum off
	Belt applicator panel		Indicates the contact status of each panel on the 3-panel belt applicator
	Vacuum applicator panel		Modifies pressure settings for massage (on Vacuum Settings screen)
	Displays Vacuum Settings screen		
	Cycle progress bar depicts cooling, warming, and massage segments and remaining treatment cycle time		

Table 1-1: Screen Display

Audible Tones

The system plays an audible tone when:

- The operator presses a button on the screen
- The operator presses a button on the applicator touch pad
- The treatment cycle begins
- The system detects an error
- The treatment cycle ends.

Control Unit Messages

Message	Response
System start-up complete	Prepare for a treatment cycle.
User cancelled treatment	Press the Next  button to start a new treatment cycle.
System error detected	Review the screen for information about the cause of the error.
Treatment complete	Remove the applicator from the patient.

Table 1-2: Control Unit Messages

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Control Unit - Rear View

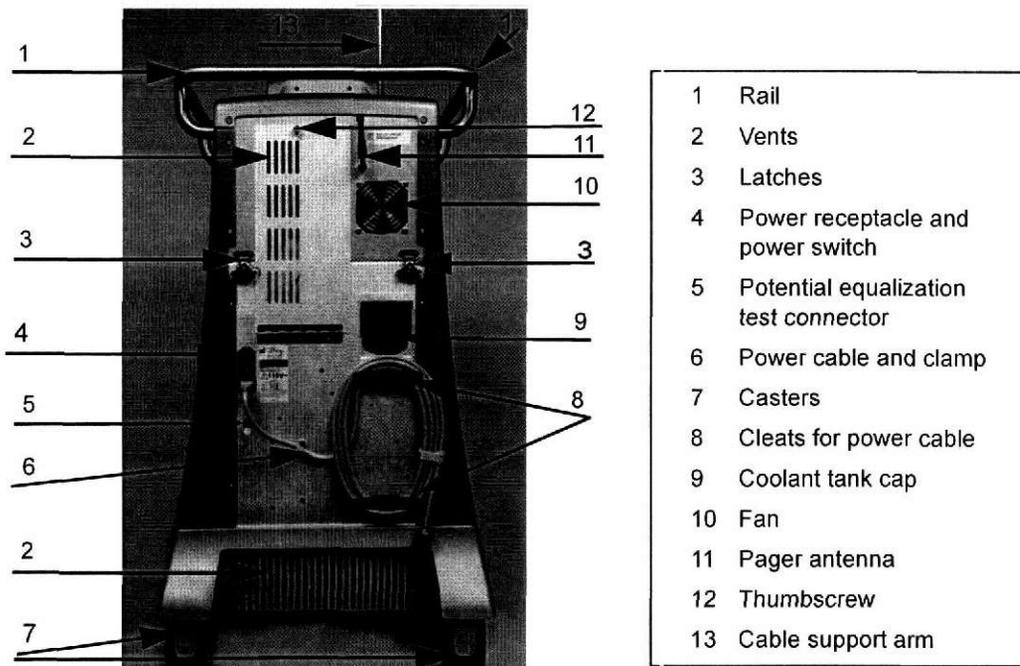


Figure 1-2: Control Unit - Rear View

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Rail

“Rail” on page 1-3

“Moving the Control Unit” on page 1-8

Vents

“Vents” on page 1-3

Latches

The latches lock the upper and lower modules of the control unit together.

“Disassembling the Control Unit” on page 3-5.

Potential Equalization Test Connector

The test connector is for use by trained personnel only.

Powering On/Off

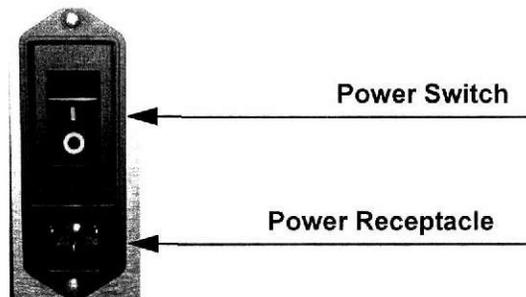


Figure 1-3: Power Switch and Power Receptacle

To power on the control unit:

- 1 Insert the power cable into the power receptacle.
- 2 Insert the thumbscrew on the cable clamp into the hole.
- 3 Using your fingers, turn the thumbscrew on the cable clamp until it is snug.
- 4 Insert the plug of the power cable into a grounded wall outlet.
- 5 Press the power switch on the back of the control unit to the On position.

The control unit powers on and displays the first screen.

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Moving the Control Unit

To move the control unit:

- 1 Power off the control unit.
- 2 Unplug the power cable from the wall outlet.
- 3 Wrap the power cable around the cleats on the back of the control unit.
Ensure that the cable does not exert force on the power cable clamp.
- 4 Release the brakes on the casters.
- 5 Push or pull the rail to move the control unit to the new location.
- 6 Engage the brakes on all four casters.

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Access Panel

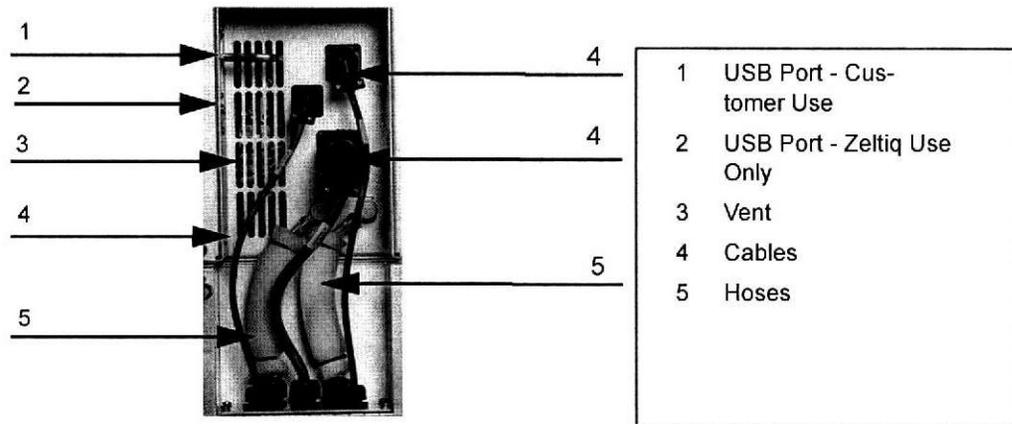


Figure 1-4: Access Panel

- Upper Port - for Customer Use: The upper USB port is intended for use with approved software provided by Zeltiq Aesthetics.
- Lower Port - for Zeltiq Use: The lower USB port is for use by Zeltiq Customer Service personnel. Do not use the service port.

- Vent

	NOTE: Vents provide airflow that reduces heat build-up inside the control unit. Ensure all vents are free from obstructions when the control unit is in operation.
-----------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------

- Cables - The cables connect the upper module to the base module and carry electrical information between the two modules.

These cables are not serviceable by the customer. To disassemble and reassemble the control unit, see "Disassembling the Control Unit" on page 3-5.

- Hoses - The hoses connect the upper module to the base module and carry coolant between the two modules.

These hoses are not serviceable by the customer. To disassemble and reassemble the control unit, see "Disassembling the Control Unit" on page 3-5.

To open the access panel:

- 1 Turn the thumb screw on the cover counterclockwise until it is loose. ("Control Unit - Rear View" on page 1-6.)
- 2 Open the cover downward.

Coolant

See "Coolant" on page 3-3.

Pager Antenna

The pager antenna sends signals to the pager. The pager antenna is powered on whenever the control unit is powered on. The pager antenna is not serviceable by the customer.

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Cable Support Arm

Drape the applicator cable over the cable support arm to minimize drag on the connections and to keep the cable out of your way. (Figure 2-4 on page 2-6)

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Zeltiq Breeze Applicators

Vacuum and belt applicators are available.

	<p>CAUTION: Always use an AcuCool sleeve and Zeltiq Gelpad with the applicator as instructed in the <i>Zeltiq AcuCool Vacuum Sleeve Directions for Use</i>, <i>Zeltiq AcuCool Belt Sleeve Directions for Use</i>, and <i>Zeltiq Gelpad Directions for Use</i>.</p>
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Vacuum Applicator

The Zeltiq Breeze Vacuum Applicator (vacuum applicator) delivers controlled cooling and warming, and optional pulsatile massage to the application site.

The vacuum applicator consists of the applicator connector, the applicator cable, and the applicator head. The vacuum applicator is used with the AcuCool Vacuum Sleeve and the Gelpad.

For information about controls for the applicator and using the applicator in a procedure, see "Zeltiq Breeze Vacuum Applicator" on page 2-13.

Belt Applicator

The Zeltiq Breeze Belt Applicator (belt applicator) delivers controlled cooling and warming, and optional vibratory massage to the application site. The belt applicator is designed to conform to the curvature of the body.

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The belt applicator consists of the applicator connector, the applicator cable, and the applicator head. The belt applicator is used with the belt sleeve and the Gelpad.

For information about controls for the applicator and using the applicator in a procedure, see "Zeltiq Breeze Belt Applicator" on page 2-18.

Pager

The Zeltiq Pager (pager) relays messages from the control unit. The pager beeps or vibrates when a new message is displayed.

- "Powering Pager On and Off" on page 1-12
- "Pager Messages" on page 1-13
- "Pager Settings" on page 1-14

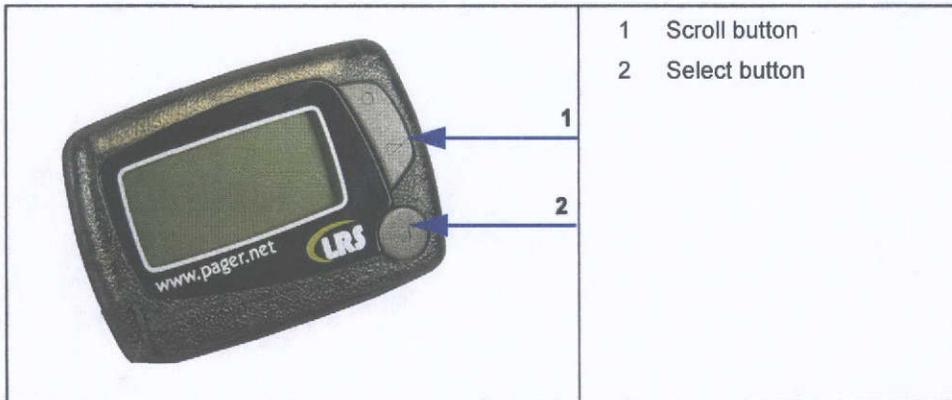


Figure 1-5: Zeltiq Pager and Controls

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Powering Pager On and Off

Power off the pager when it will be idle for an extended period of time, or at the end of the work day.

To power on the pager:

- 1 Press and hold the top of the **Scroll** button until the pager displays **Power On? - No**.
- 2 Press the **Scroll** button to highlight **Yes**.
- 3 Press the **Select** button.
- 4 The pager powers on and displays a welcome message.
- 5 Wait until the screen clears.
The pager is ready for use.

To power off the pager:

- 1 Press the **Scroll** button.
A message is displayed.
- 2 Press the top of the **Scroll** button repeatedly until **Power Off** is displayed.
- 3 Press the **Select** button.
- 4 Press the **Scroll** button to highlight **Yes**.
- 5 Press the **Select** button.
The pager displays **Goodbye** and powers off.

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Pager Messages

To read pager messages:

- 1 Press the **Scroll** button.

A message is displayed with the following information:

[n/nn]: Number of current message / total message count

MM/DD/YYYY: Date of message (month / day / year)

H/MM or **HH/MM**: Time when message was received (hour /minutes)



NOTE: If no messages are available, the pager displays **No Messages**.

- 2 To read the next message, press the bottom of the **Scroll** button.

Pager Messages

Message	Description	Action
LRS Paging. What are you waiting for?	The pager has powered on and is ready for use.	n/a
System Startup Complete	The control unit has started up and is ready for use.	n/a
Treatment Complete	The cycle has ended.	Return to the control unit.
Treatment Cancelled	The cycle was cancelled.	Return to the control unit.
Patient Request	The patient pressed the call button.	Return to the patient.
System ERROR detected	An error was detected.	Return to the control unit.
Treatment Stopped - ERROR	An error was detected and the cycle was cancelled.	Return to the control unit.
Goodbye	The pager is powering off.	n/a

Table 1-3: Pager Messages

Pager Settings

To view and modify pager settings:

- 1 Press the top of the **Scroll** button.

A message is displayed.

	NOTE: If no messages are stored, the pager displays No Messages .
-----------------------------------------------------------------------------------	--------------------------------------------------------------------------

- 2 To cycle through the list of functions, press the top of the **Scroll** button again.

A function is displayed.

- 3 To select the displayed function, press the **Select** button.

A message is displayed. (Table "Pager Settings," on page 14)

- 4 Press the top or bottom of the **Scroll** button to change selections or settings.

- 5 Press the **Select** button to save changes.

Function	Description
Read All	Display messages and envelope information for each message. Press the Select or Scroll button to view the next item.
Power Off	Power off the pager.
Set Keytone	A beep sounds each time you press a key on the pager. (On/Off)
Set Contrast	Modify contrast settings for the pager screen.
Auto On/Off	Set start and end times for automatic power-on and power-off.
Set Time/Date	Modify time and date settings.

Table 1-4: Pager Settings

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Function	Description
Set Alert Mode	Set alert mode and characteristics. Vibe (vibration): <ul style="list-style-type: none"> • Set Vibe Strength: Strong/Weak • Set Vibe Pulse: Cnst (Constant) /P1/P2/P3 (P=Pulse) • Set Alert Time: 1 - 10 seconds Beep <ul style="list-style-type: none"> • Set Beep Type: Loud/Soft • Set Alert Time: 1 - 10 seconds Both <ul style="list-style-type: none"> • Set Vibe Strength: Strong/Weak • Set Alert Time: 2, 4, 6, 8, or 10 seconds
Stop Watch	Start, stop, and clear stop watch.
View Calendar	View monthly calendars for the year.
Delete All	Delete all messages.

Table 1-4: Pager Settings

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Call Button

When the operator is out of the room during a cycle, the patient can press the call button to contact the operator via the pager. When the call button is pressed, the control unit beeps and the pager displays a message. ("Pager Messages" on page 1-13)

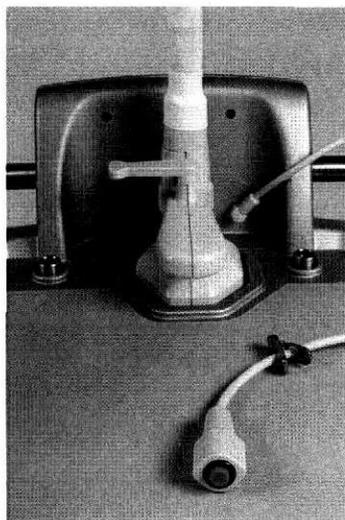


Figure 1-6: Call Button

To set up the call button:

- 1 Insert the connector for the call button into the jack on the back of the screen housing. (Figure 1-6, "Call Button," on page 1-16)
- 2 Clip the cable in a location that is convenient for the patient.

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Supplies



NOTE: Used sleeves and Gelpads are considered medical waste. Dispose of used sleeves and Gelpads according to your site's medical waste protocols.

AcuCool Sleeves

Each sleeve is programmed with several profiles. Each profile includes a fixed number of timed segments of cooling, warming, and optional massage, or a combination thereof. ("About Profiles" on page 2-9)
Each sleeve is approved for single-patient use only.

AcuCool Vacuum Sleeve

Use the vacuum sleeve with the control unit, vacuum applicator, and Gelpad. The vacuum sleeve provides an interface and a physical barrier between the vacuum applicator and the patient's skin.

See also:

- *Zeltiq AcuCool Vacuum Sleeve Directions for Use*

AcuCool Belt Sleeve

Use the belt sleeve with the control unit, belt applicator, and Gelpad. The belt sleeve provides an interface and a physical barrier between the applicator and the patient's skin.

See also:

- *Zeltiq AcuCool Belt Sleeve Directions for Use*

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Gelpad

The Gelpad provides thermal contact between the applicator and the patient's skin. The Gelpad is intended for use on a single application site only. The Gelpad is applied to the application site on the patient's skin before the applicator is placed on the application site.

See also:

Zeltiq Gelpad Directions for Use

Coolant

The control unit requires an adequate supply of coolant. When the coolant level is low, a Recoverable Exception message is displayed. ("Coolant" on page 3-3)

	CAUTION: The use of unauthorized coolant has not been tested. Always use coolant authorized by Zeltiq.
------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------

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Chapter 2: Zeltiq Procedures

This chapter provides detailed instructions on performing a Zeltiq Procedure (procedure) with the Zeltiq Breeze Control Unit (control unit) and the Zeltiq Breeze Belt Applicator (belt applicator) or the Zeltiq Breeze Vacuum Applicator (vacuum applicator).

Contents

- "About the Zeltiq Procedure" on page 2-2
- "Set up the Control Unit" on page 2-4
- "Position the Applicator" on page 2-13
- "Perform a Zeltiq Procedure" on page 2-20

See Also

- *Zeltiq AcuCool Vacuum Sleeve Directions for Use*
- *Zeltiq AcuCool Belt Sleeve Directions for Use*
- *Zeltiq Gelpad Directions for Use*

For information on messages displayed on the screen and to resolve issues, see "Control Unit Messages" on page A-1.

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About the Zeltiq Procedure

The Zeltiq™ procedure (procedure) consists of one or more treatment cycles. Each treatment cycle is controlled by a profile, which defines the timed segments of cooling, heating, and/or massage. For each treatment cycle, choose a profile for one application site on the patient's skin.

The profiles are defined by Zeltiq Aesthetics and cannot be modified by the customer. Each AcuCool sleeve is designed for use on a single patient and is programmed with a selection of profiles and a defined number of uses. After a certain number of treatment cycles, the sleeve expires and cannot be used again.



CAUTION: Performing multiple treatment cycles on one application site may result in mild tissue injury (e.g. bruising). Perform only one treatment cycle per application site.

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Overview of the Zeltiq Procedure

To perform a Zeltiq procedure:

- 1 Set up the control unit.
- 2 Identify an application site on the patient.
- 3 Install the applicator and AcuCool sleeve.
- 4 Clean the application site with an alcohol wipe.
- 5 Apply a Gelpad to the application site.
- 6 Select a profile.
- 7 Perform a treatment cycle.
- 8 Discard the used Gelpad according to your site's medical waste protocols.
- 9 Optional:
Clean a second application site and apply a new Gelpad.
Set up the applicator and sleeve on the new site.
Repeat steps 6 and 7.



WARNING: If the Zeltiq System detects that the rate of heat flux has exceeded acceptable limits, the system interrupts the cycle.

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Set up the Control Unit

To set up the control unit:

- 1 Position the control unit next to the bed or chair to be used for the procedure.
- 2 Engage the brakes on all four casters.
- 3 Insert the power plug into a grounded outlet.
- 4 (Optional) Set up the pager. ("Pager" on page 1-11)
- 5 (Optional) Set up the patient call button. ("Call Button" on page 1-16)
- 6 Power on the control unit.

The **Applicator?** message is displayed.

Attach the Applicator

To attach the applicator:

- 1 Ensure the cable support arm is installed on the side of the control unit that will be next to the procedure bed or chair.
To install the cable support arm, insert the straight end into the jack. (Figure 2-4 on page 2-6.)
- 2 Place the applicator on top of the control unit with the panels facing upward. (Figure 2-1 on page 2-5)

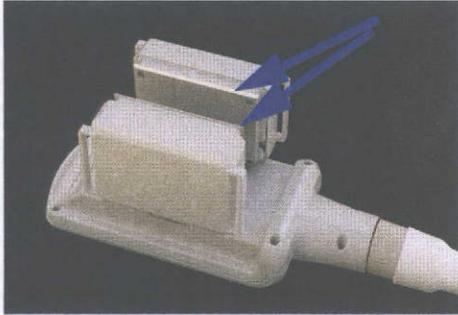


Figure 2-1: Panels on Vacuum Applicator and Belt Applicator

- 3 Position the connector above the connector plate.
- 4 With the locking lever in the Unlocked position, press the applicator connector down onto the connector plate gently but firmly.

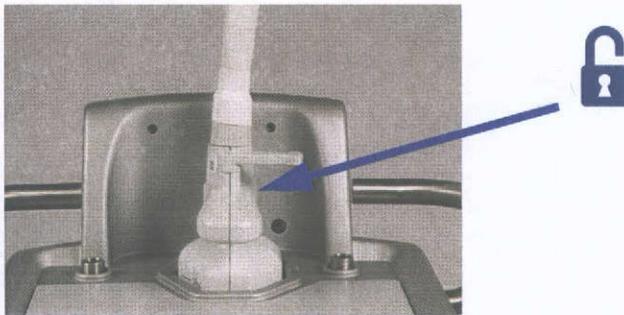


Figure 2-2: Connector Unlocked with Icon

- 5 When the connector meets resistance, stop pressing down.
- 6 Turn the locking handle 180° clockwise to the Locked position.
The connector is pulled into the connector plate and locked in place.
(Figure 2-3 on page 2-6)

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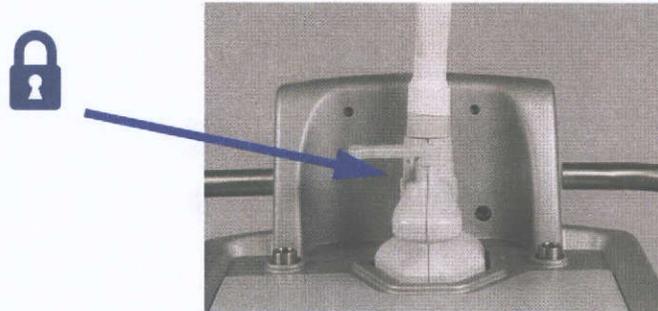


Figure 2-3: Connector Locked with Icon

The **Authenticating...** message is displayed. When the process is complete, the **✓ Vacuum Applicator** message is displayed.

- 7 Slip the applicator connector cable into the hook at the top of the cable support arm. (Figure 2-4 on page 2-6)

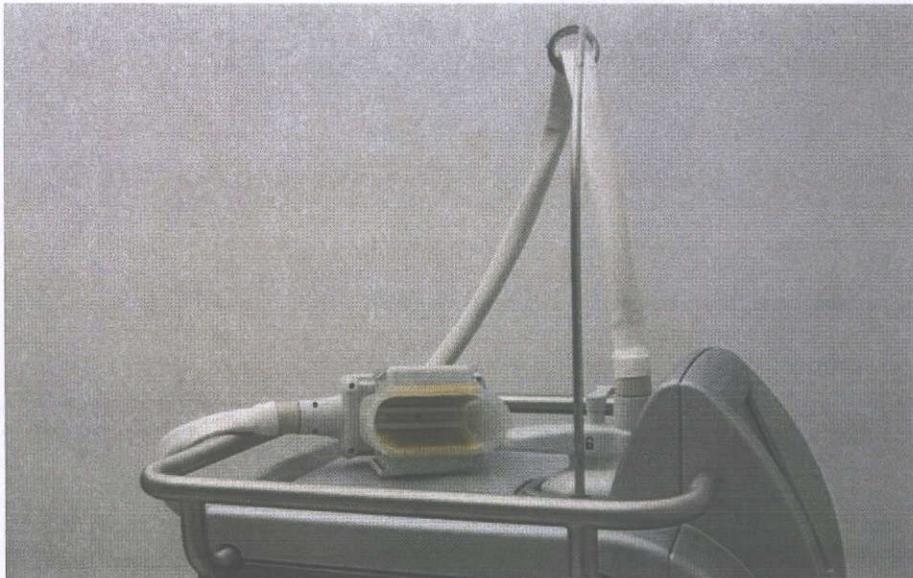


Figure 2-4: Control Unit, Cable Support Arm, and Vacuum Applicator

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Connect a Sleeve

The AcuCool™ sleeve has a fixed number of treatment cycles and an overall time limit. When all treatment cycles have been performed or the time limit has been reached, the sleeve is expired and cannot be used again.

The time countdown begins when you start the first treatment cycle. If you take a long break after a treatment cycle, the sleeve could expire before you perform the remaining treatment cycle.

To connect a sleeve:

- 1 Read the appropriate *Directions for Use* for the sleeve you are using. 

- 2 After you connect the sleeve, the



message is displayed with information on the number of treatment cycles remaining.

If the sleeve is expired, a Recoverable Exception is displayed. Follow the instructions on the screen. ("Control Unit Messages" on page A-1)

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Apply the Gelpad

	CAUTION: Do not allow any liquid or gel to touch the connector.
-----------------------------------------------------------------------------------	-----------------------------------------------------------------

- 1 Clean the application site with an alcohol wipe.
- 2 Apply the Gelpad as described in the *Zeltiq Gelpad Directions for Use*. 
- 3 When the Gelpad is in place, press the  button.

The screen indicates that the applicator, sleeve, and Gelpad are ready. (Figure 2-5 on page 2-8)



Figure 2-5: Gelpad Ready (Vacuum Example)

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- 4 Press the  button.

The profile screen is displayed.



Figure 2-6: Profile Screen (Vacuum Example)

About Profiles

- “Profiles for a Vacuum Applicator” on page 2-10
- “Profiles for a Belt Applicator” on page 2-11
- “To select a profile:” on page 2-12

Elements of a Profile

A profile contains the following elements:

Element	Description
CIF	The rate of heat extraction. A high CIF represents a higher rate of heat extraction or a colder treatment cycle.
Time	The time of the treatment cycle, in minutes.
Massage	Inclusion of massage segment (Massage/No massage)

Table 2-1: Elements of a Profile

Profiles for a Vacuum Applicator

Select an appropriate profile.

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Y = approved Dash = not approved	Minimize pain and thermal injury during laser and dermatological treatments	Local anesthetic for procedures that induce minor local discomfort	Minimize pain after surgery or trauma	Temporary relief of minor aches, pains, muscle spasms	Temporary improvement in local circulation	Temporary reduction in appearance of cellulite
CIF: 30.3 (-60.5 mW/cm ²) Min: 15 Massage: No	Y	Y	--	--	--	--
CIF: 30.3 (-60.5 mW/cm ²) Min: 30 Massage: No	Y	Y	Y	Y	--	--
CIF: 30.3 (-60.5 mW/cm ²) Min: 60 Massage: No	--	--	Y	Y	--	--
CIF: 32.9* (-63.6 mW/cm ²) Min: 60 Massage: Yes	--	--	--	--	Y	Y
CIF: -0.6 (6.2 mW/cm ²) Min: 30 Massage: No	--	--	Y	Y	--	--
CIF: -0.6 (6.2 mW/cm ²) Min: 60 Massage: No	--	--	Y	Y	--	--
CIF: -0.6** (6.2 mW/cm ²) Min: 60 Massage: Yes	--	--	--	Y	--	--

Table 2-2: Profiles for a Vacuum Applicator

* This profile includes 55 minutes at CIF 32.9, a 2-minute transition to CIF -1.4, and 3 minutes of massage at CIF -1.4.

**This profile includes a 2-minute ramp to CIF -0.6, followed by 58 minutes at CIF -0.6 with massage.

Profiles for a Belt Applicator

Select an appropriate profile.

Y = approved Dash = not approved	Minimize pain and thermal injury during laser and dermatological treatments	Local anesthetic for procedures that induce minor local discomfort	Minimize pain after surgery or trauma	Temporary relief of minor aches, pains, muscle spasms	Temporary improvement in local circulation	Temporary reduction in appearance of cellulite
CIF: 20.5 (-34.2 mW/cm ²) Min: 15 Massage: No	Y	Y	--	--	--	--
CIF: 20.5 (-34.2 mW/cm ²) Min: 30 Massage: No	Y	Y	Y	Y	--	--
CIF: 20.5 (-34.2 mW/cm ²) Min: 60 Massage: No	--	--	Y	Y	--	--
CIF: 21.1 * (-35.9 mW/cm ²) Min: 60 Massage: Yes	--	--	--	--	Y	Y
CIF: -0.4 (3.5 mW/cm ²) Min: 30 Massage: No	--	--	Y	Y	--	--
CIF: -0.4 (3.5 mW/cm ²) Min: 60 Massage: No	--	--	Y	Y	--	--
CIF: -0.4 (3.5 mW/cm ²) Min: 60 Massage: Yes	--	--	--	Y	--	--

Table 2-3: Profiles for a Belt Applicator

* This profile includes 55 minutes at CIF 21.1, a 2-minute transition to CIF -0.8, and 3 minutes of massage at CIF -0.8.

**This profile includes a 2 minute ramp to CIF -0.4, followed by 58 minutes at CIF -0.4 with massage.

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To select a profile:

- 1 On the profile screen, press the top row or the  button to the right of the top row.

The drop-down list of available profiles is displayed. (Table 2-2 on page 2-10 and Table 2-3 on page 2-11)



Figure 2-7: Profile List (Vacuum Example)

- 2 Press the desired profile.

The drop-down list is hidden and the selected profile is displayed.

- 3 Press the  button.

The start treatment cycle screen is displayed. (Figure 2-8 on page 2-12)



Figure 2-8: Start Treatment Cycle Screen (Vacuum Example)

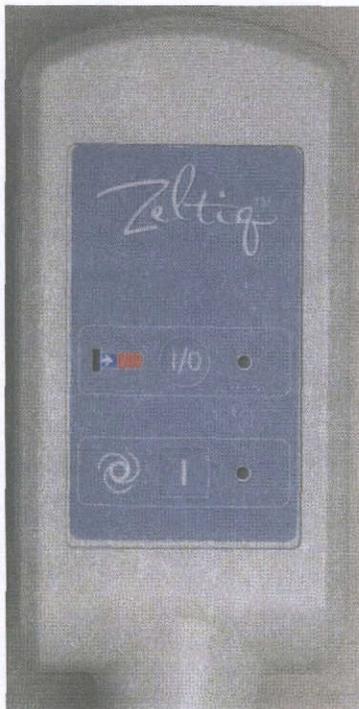
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Position the Applicator

- “Zeltiq Breeze Vacuum Applicator” on page 2-13
- “Zeltiq Breeze Belt Applicator” on page 2-18

Zeltiq Breeze Vacuum Applicator

Controls on the Vacuum Applicator



	Treatment cycle indicator
	Start/stop treatment cycle button
	Treatment cycle status indicator Solid blue: Ready to start cycle Flashing blue: Cycle in progress Flashing blue (fast): Error, cycle interrupted
	Vacuum indicator
	Start/stop vacuum button
	Vacuum status indicator Green light: Vacuum is on No light: Vacuum is off

Figure 2-9: Controls on the Vacuum Applicator

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Icons - Profile and Vacuum Screen

On the screen, vacuum pressure is expressed as inches of mercury times a factor of ten. For example, "6 in Hg" is displayed as 60. (Figure 2-10 on page 2-14)

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Figure 2-10: Profile and Vacuum Screen

	Tools: Press to display the Vacuum Settings controls
	Vacuum indicator
	Vacuum status Press to toggle vacuum on and off
	Vacuum pressure: press - and + buttons to decrease and increase vacuum pressure

Table 2-4: Controls - Profile and Vacuum Screen

Icons - Vacuum Settings Screen



Figure 2-11: Vacuum Settings Screen

	Message
	Message status Press to toggle message between off and on
	Press the down and up arrows to decrease and increase the Max and Min pressure for message

Table 2-5: Controls - Vacuum Settings Screen

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Position the Vacuum Applicator



WARNING: If the Gelpad slips and the sleeve comes into prolonged direct contact with the patient's skin, tissue injury may result. Inspect the Gelpad and applicator to ensure that the Gelpad extends beyond the borders of the panels.

To position the vacuum applicator:

- 1 Press the  button on the applicator touch pad.

The vacuum is activated and the  button is displayed.

- 2 Place the vacuum applicator over the Gelpad on the application site.

- 3 (Optional) Press the  buttons to increase or decrease the vacuum pressure.

Vacuum Pressure for Massage

If the profile includes a massage segment, you can test the vacuum pressure for massage to prepare the patient for the sensations of massage and to ensure the settings will keep the applicator in place during the procedure.



CAUTION: Excessive vacuum pressure for massage may cause discomfort and/or mild tissue injury (e.g. bruising). Use massage pressure settings that are acceptable for patient comfort.

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To test the vacuum pressure for massage:

- 1 When the applicator is on the application site and the tissue is pulled up inside the sleeve, press the  button.

The **Vacuum Settings** screen is displayed. (Figure 2-11 on page 2-15)

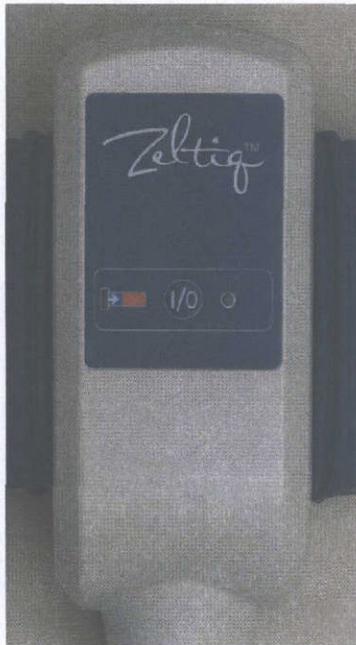
- 2 Press the  button to turn massage on and test the settings.
- 3 Press the **Max** and **Min** arrow buttons during the procedure if needed to ensure adequate vacuum pressure for massage and to enhance patient comfort.
- 4 Press the  button to turn massage off.
- 5 Press the  button to close the **Vacuum Settings** screen.
- 6 If necessary, adjust the position of the vacuum applicator and modify the vacuum pressure and vacuum pressure for massage settings.
- 7 If you turn on vacuum pressure and then remove the vacuum applicator from the site, clean up any remaining gel and apply a new Gelpad. (*Zeltiq Gelpad Directions for Use*)

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Zeltiq Breeze Belt Applicator

Controls on the Belt Applicator

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	Treatment cycle indicator
	Start/stop treatment cycle button
	Treatment cycle status indicator Solid blue: Ready to start cycle Flashing blue: Cycle in progress Flashing blue (fast): Error, cycle interrupted

Figure 2-12: Controls on the Belt Applicator

Screen Controls for the Belt Applicator

	Start: Press to start the treatment cycle
	Cancel: Press to cancel the treatment cycle
	Tools: (Not used for the Zeltiq Breeze Belt Applicator)
	Contact Indicator (Belt) Indicates quality of contact between the applicator and the application site

Table 2-6: Screen Controls for the Belt Applicator

To position the belt applicator:

- 1 Place the belt applicator over the Gelpad on the application site.
- 2 Use the strap to secure the belt applicator in place.
- 3 Review the contact indicator on the screen to confirm the applicator is in good contact with the application site. (“Screen Controls for the Belt Applicator” on page 2-19)
- 4 If necessary, adjust the position of the belt applicator and confirm the quality of contact.



WARNING: If the sleeve comes into prolonged direct contact with the patient’s skin, tissue injury may result. Inspect the Gelpad and applicator to ensure that the Gelpad extends beyond the borders of the panels.

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Perform a Zeltiq Procedure

A Zeltiq procedure may consist of one or more treatment cycles.

- "About Sleeve Limits" on page 2-20
- "Start a Treatment Cycle" on page 2-21
- "Perform Another Treatment Cycle (Optional)" on page 2-22
- "Cancel a Treatment Cycle (Optional)" on page 2-24
- "Complete a Treatment Cycle or Procedure" on page 2-25

About Sleeve Limits

The AcuCool sleeve has a fixed number of treatment cycles and an overall time limit. When all treatment cycles have been performed or the time limit has been reached, the sleeve is expired and cannot be used again.

The time countdown begins when you start the first treatment cycle. If you take a long break after a treatment cycle, the sleeve could expire before you perform the remaining treatment cycle.



NOTE: Used sleeves and Gelpads are considered medical waste. Dispose of used sleeves and Gelpads according to your site's medical waste protocols.

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Start a Treatment Cycle

To start a treatment cycle:

- 1 With the Gelpad, AcuCool sleeve, and applicator in position, press the  button.



WARNING: (Vacuum procedure only) For best results, ensure that tissue is pulled up inside the sleeve.

- 2 Select a profile and press the  button.

The Start treatment cycle screen is displayed. (Figure 2-8 on page 2-12)



Figure 2-13: Start Treatment Cycle Screen (Vacuum Example)

- 3 To test the vacuum pressure for massage, see “Vacuum Pressure for Massage” on page 2-16.
- 4 To change the vacuum settings for the treatment cycle, see “Icons - Vacuum Settings Screen” on page 2-15.

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- 5 To begin the treatment cycle, press the  button.

The treatment cycle begins.

The LED flashes blue on the applicator touch pad.

When the treatment cycle begins and when it is complete, the control unit emits an audible tone and displays a Treatment Summary message.

For information on messages displayed on the screen and to resolve issues, see "Control Unit Messages" on page A-1.

Perform Another Treatment Cycle (Optional)

To perform another treatment cycle on the same patient:

- 1 When the first treatment cycle is complete, remove the applicator and sleeve from the patient.

(Vacuum procedure only) Grasp the applicator and press the  button on the applicator touch pad to turn the vacuum off.



CAUTION: When the vacuum is turned off, the applicator may disengage from the patient. The applicator could fall and be damaged or could cause injury. Grasp the head of the applicator firmly before turning off the vacuum.

- 2 Place the applicator head on top of the control unit with the panels down.
Allow gel to drain onto a towel or other absorbent material.
- 3 Wipe gel from the patient's skin.

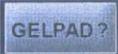
- Discard the used Gelpad and clean up any remaining gel. (“Cleaning” on page 3-2)

 NOTE: Used sleeves and Gelpads are considered medical waste. Dispose of used sleeves and Gelpads according to your site’s medical waste protocols.

- Press the  button.

	If the sleeve is active	If the sleeve is expired
The  message is displayed.		A Recoverable Exception message is displayed. Connect a new sleeve.

- Clean the next application site with an alcohol wipe.
- Apply a new Gelpad. 

Read the *Zeltiq Gelpad Directions for Use* before applying the Gelpad.
- Press the  button and press the  button.
- (Vacuum procedure only) Press the  button on the applicator touch pad.

The vacuum is activated and the  button is displayed.
- Place the applicator over the Gelpad on the application site and press the  button.
- (Vacuum procedure only) For best results, ensure that tissue is pulled up inside the sleeve.
- Select a profile and press the  button.
- To begin the treatment cycle, press the  button.

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The treatment cycle begins.

The LED flashes blue on the applicator touch pad.

When the treatment cycle is complete, the control unit emits an audible tone and displays a Treatment Summary message.

Cancel a Treatment Cycle (Optional)

To cancel a treatment cycle:

- 1 (Optional) To cancel a treatment cycle in progress, press the **Cancel** button. 



Figure 2-14: Treatment Cycle in Progress Screen

The treatment cycle is cancelled and the **User cancelled treatment** message is displayed.

The number of treatment cycles on the sleeve is reduced by one.

- 2 Press the  button.
- 3 To perform another treatment cycle, see "Perform Another Treatment Cycle (Optional)" on page 2-22.

- 4 If there are no more treatment cycles to perform, or to move the control unit to another location, press the power switch. (Figure 2-15 on page 2-26)

Complete a Treatment Cycle or Procedure



NOTE: Used sleeves and Gelpads are considered medical waste. Dispose of used sleeves and Gelpads according to your site's medical waste protocols.

To complete a treatment cycle or procedure:

- 1 when the screen displays a Treatment Summary message:
(Vacuum applicator) Grasp the applicator and press the  button on the applicator touch pad to turn the vacuum off.
- 2 Remove the applicator from the application site.
- 3 Place the applicator head on top of the control unit with the panels down.
Allow gel to drain onto a towel or other absorbent material.
- 4 Wipe gel from the patient's skin.
- 5 Remove the sleeve from the applicator.
- 6 Discard the used sleeve and Gelpad.
- 7 Use an alcohol wipe to remove residue from the panels and plastic housing of the applicator. ("Cleaning" on page 3-2)
- 8 To power off the control unit, press the power switch. (Figure 2-15 on page 2-26)

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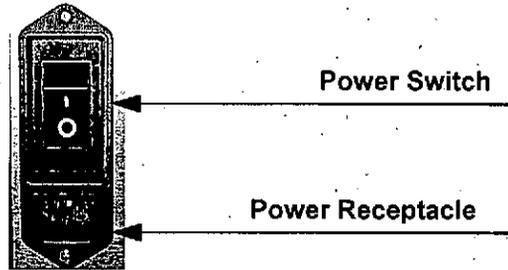


Figure 2-15: Power Switch and Power Receptacle

Chapter 3: Cleaning and Maintenance

Contents

- "Ordering Supplies and Parts" on page 3-1
- "Cleaning" on page 3-2
- "Maintenance" on page 3-3
- "Disassembling the Control Unit" on page 3-5
- "Customer Service" on page 3-13

Ordering Supplies and Parts

To order supplies such as AcuCool sleeves and Gelpads, and to order replacement parts, go to the Zeltiq Online Store:

www.zeltiq.com

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Cleaning

	CAUTION: The use of an unapproved cleaning solution or method on the control unit or applicator may result in damage. Always use approved products and follow the guidelines below.
-----------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Approved Products

The following products are approved for cleaning the control unit and applicators:

- Isopropyl alcohol
- Mild detergent and warm water
- PDI Sani Cloth Plus wipes

Cleaning the Control Unit and System Components

- Unplug the control unit before cleaning.
- Use sterilization wipes or spray the cleaning agent on a soft wipe, paper towel, or equivalent material.

	CAUTION: Do not spray or spill any fluid directly on any part of the control unit, applicators, or supplies.
-------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------

	CAUTION: Do not submerge the applicator or any other part of the Zeltiq System in any liquid.
-------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------

- Do not use excessive amounts of fluid.
- Do not apply cleaning solution to the electrical connections.
- After cleaning the system components, dry them with a soft cloth to remove any cleaning residues.
- Do not sterilize the control unit, applicator, AcuCool sleeve, or any other system components.

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Maintenance

Coolant

Coolant circulates between the control unit and the applicator to remove heat from the application site. When you connect a new applicator, it takes up a significant amount of coolant. Also, when you disconnect an applicator, or disconnect the hoses on the access panel to prepare for shipping a module, a small amount of coolant may be lost.

When the level of coolant is low, the control unit displays a message. It is safe to add coolant while the control unit is powered on.



CAUTION: The use of unauthorized coolant has not been tested. Always use coolant authorized by Zeltiq.

To add coolant:

- 1 Locate the coolant tank cap. (Figure 3-1 on page 3-4)
- 2 Press down on the recessed end of the blue lever on the coolant tank cap. (Figure 3-2 on page 3-4)

The handle flips up. (Figure 3-3 on page 3-4)

- 3 Turn the blue handle counter-clockwise until the cap disengages.
- 4 Remove the cap.
- 5 Pour coolant into the tank.

The amount of additional coolant that is required can vary. To avoid spillage, watch the coolant as you pour. Listen for changes in the sound.

- 6 Replace the cap and tighten it just until snug.

When the vacuum is activated, it pulls the cap in tighter. If you overtighten the cap, it could become too tight to loosen.

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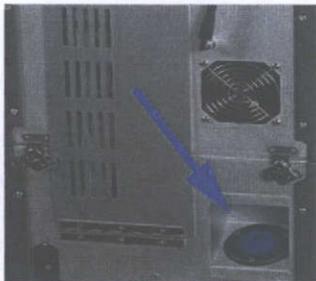


Figure 3-1: Coolant Tank Cap

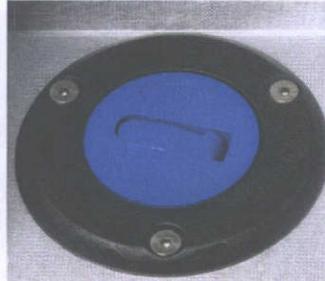


Figure 3-2: Handle Recessed



Figure 3-3: Handle Up

Disassembling the Control Unit

The control unit consists of an upper module and a base module. Disassemble the control unit to prepare to ship either module to the factory for repair or replacement.

- "Latches" on page 3-5
- "Cables and Hoses" on page 3-7
- "Remove Upper Module" on page 3-9

Latches

To disassemble the control unit:

- 1 Power off the control unit.
- 2 Engage the brakes on all four casters.
- 3 Disconnect the power cord from the control unit.
- 4 Wrap the power cord around the cleats and secure it with the velcro strap. (Figure 3-4 on page 3-6)
- 5 Open the storage drawer (Figure 3-4 on page 3-6) and disconnect the latches on the front of the control unit.
- 6 Disconnect the latches on the back of the control unit.

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7 To disconnect a latch:

Flip the handle of the latch upward and turn it counterclockwise until the top of the clasp disengages. (Figure 3-6 on page 3-6)

Pull the handle back and let it hang downward. (Figure 3-7 on page 3-6)

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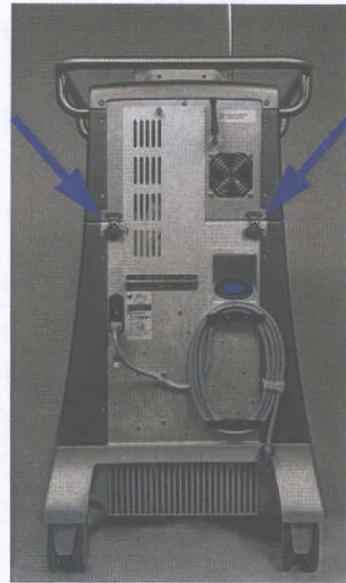


Figure 3-4: Locations of Latches and Cleats

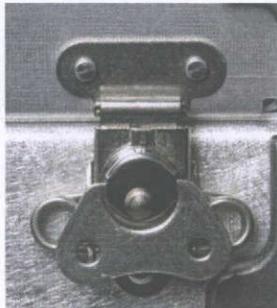


Figure 3-5: Locked

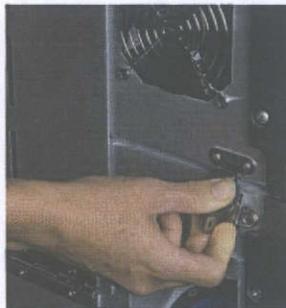


Figure 3-6: Unlocking

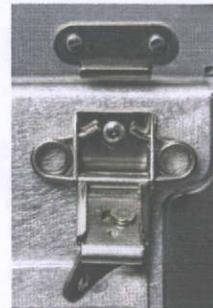


Figure 3-7: Unlocked

Cables and Hoses

To disconnect cables and hoses:

- 1 Turn the thumbscrew on the cover of the access panel.
(Figure 3-8 on page 3-7)
- 2 Let the cover hang down, exposing the cables and hoses.
(Figure 3-9 on page 3-7)
- 3 Working from left to right, disconnect the cables and then the hoses.

See "To disconnect a cable:" on page 3-8 and "To disconnect a hose:" on page 3-8.

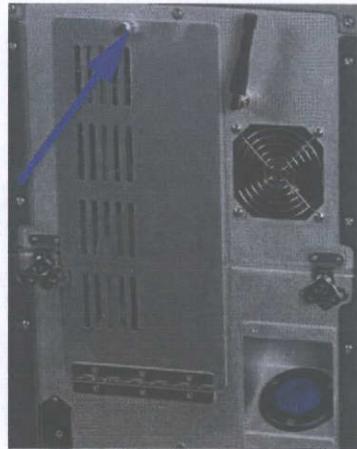


Figure 3-8: Access Panel Cover



Figure 3-9: Cables and Hoses

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To disconnect a cable:

- 1 Locate the ring that is closest to the back of the access panel.
- 2 Turn the ring counterclockwise until it moves freely.
- 3 Pull the ring off the connector.

To disconnect a hose:

- 1 Squeeze the metal clasp at the top of the hose connector.
(Figure 3-10 on page 3-8)
- 2 Pull back until the hose connector disengages from the post.



NOTE: A small amount of coolant may drip from the hoses. Wipe up coolant with a soft cloth.



Figure 3-10: Cable Connector with Metal Clasp

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Remove Upper Module

To remove the upper module:

CAUTION: The upper and base modules of the control unit are heavy. Do not attempt to lift either module by yourself. These procedures require two people.

- 1 Engage the brakes on all four casters.
- 2 Prepare a place to put the upper module.
- 3 Position each person on one side of the control unit.
- 4 Have each person grasp the rail with two hands.
- 5 Lift the upper module. (Figure 3-11 on page 3-9)



Figure 3-11: Lifting the Upper Module

- 6 Walk past the base module and put the upper module down. (Figure 3-12 on page 3-10)

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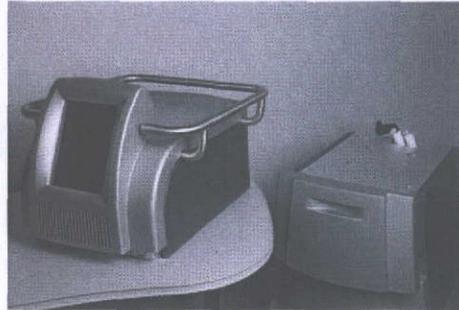


Figure 3-12: Upper Module and Base Module Disassembled

Assembling the Control Unit



CAUTION: The upper and base modules of the control unit are heavy. Do not attempt to lift either module by yourself. This procedure requires two people.

To install the upper module:

- 1 Engage the brakes on all four casters.
- 2 Ensure the power cord is disconnected from the control unit.
- 3 Ensure the cables and hoses that are attached to the base module are out of the way.
- 4 Place the base module in front of the upper module. (Figure 3-13 on page 3-11)
- 5 Grasp the bar on the upper module and lift the upper module into position on top of the base module. (Figure 3-11 on page 3-9)
- 6 Ensure the cables and hoses are clear. (Figure 3-14 on page 3-11)
- 7 Connect the latches, cables, and hoses. ("Connecting Latches, Hoses, and Cables" on page 3-12)



Figure 3-13: Positioning the Upper Module



Figure 3-14: Ensuring Cables and Hoses are Clear

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Connecting Latches, Hoses, and Cables

To connect the latches:

- 1 Place the top clasp over the top hook.
- 2 Flip the handle of the latch outward.
- 3 Turn the handle clockwise until the top clasp is snug against the hook.
- 4 Press the handle down.

To connect the hoses and cables:

- 1 Start with the hose on the right.
- 2 Press the hose into the jack.
- 3 Repeat for the hose on the left.
- 4 Press the cable connector on the right over the post.
- 5 Turn the ring clockwise until it is snug. Do not overtighten.
- 6 Repeat for the rest of the cables, working from right to left.
- 7 Close the cover of the access panel.
- 8 Turn the thumbscrew to the right just until it is snug. Do not overtighten.

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Customer Service

To report issues with the performance or use of your Zeltiq System, contact Zeltiq Customer Service at 1-888-935-8471 (1-888-ZELTIQ1).

Routine Issues

For questions regarding device performance or to report issues that do not interfere with current patient procedures:

- Call during regular business hours, 6 am to 6 pm, Pacific Time, Monday through Friday. Calls are answered in the order received.

Urgent Issues

To report safety concerns or issues that interfere with current patient procedures:

- Call at any time. Outside regular business hours (above), leave a voicemail. A technician will be paged and will return your call promptly.

1-888-935-8471 (1-888-ZELTIQ1)

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Appendix A: Control Unit Messages

This appendix lists the messages that can be displayed on the screen and comments, including the suggested user action, if any. For assistance with any message not listed here, call Zeltiq Customer Service.

Message	Comments
[] lost communication with [].	Call Zeltiq Customer Service.
Applicator authentication failed. Replace Applicator.	Connect a new applicator.
Applicator disconnected.	Reconnect applicator.
Chiller fan failed. Call Service.	Call Zeltiq Customer Service.
Chiller pump failed. Call Service.	Call Zeltiq Customer Service.
Chiller RTD has a short. Call Service.	Call Zeltiq Customer Service.
Chiller RTD has an open. Call Service.	Call Zeltiq Customer Service.
Chiller tank low. Add coolant.	Add coolant. See "Coolant" on page 3-3.
Control unit authentication failed.	Call Zeltiq Customer Service.
Error enabling treatment. Replace sleeve.	Connect a new sleeve.
Error reading profiles - read time-out.	Reconnect the sleeve or connect a new sleeve.
Restarted treatment too soon. Wait one minute and retry.	
Sleeve authentication failed. Replace Sleeve.	Connect a new sleeve.
Sleeve defective.	Replace sleeve.
Sleeve disconnected.	Ensure there is no gel on the sleeve connector. Reconnect or replace the sleeve.
Sleeve is expired. Replace sleeve.	Connect a new sleeve.

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PL-12689-02

A-1

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K090094, S2 Response

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Message	Comments
Sleeve problem. Replace sleeve.	Connect a new sleeve.
Stopped with poor quality on channels [].	Connect a new sleeve.
Stopped with poor quality.	Connect a new sleeve.
Stopped with temperature anomaly on channels []. Remove applicator from patient.	Remove applicator from patient and then call Zeltiq Customer Service.
Stopped with temperature anomaly. Remove applicator from patient.	Remove applicator from patient and then call Zeltiq Customer Service.
TEC current exceeded limit. Call Service.	Call Zeltiq Customer Service.
TEC link mask mismatch.	Power the system off and on. If the problem persists, call Zeltiq Customer Service.
TEC link mask mismatch. Received []. Expected [].	Call Zeltiq Customer Service.
TEC voltage exceeded limit. Call Service.	Call Zeltiq Customer Service.
Temperature fault: Channel [].	Call Zeltiq Customer Service.
Temperature fault.	Call Zeltiq Customer Service.
Temperature overshoot: Channel [] defective.	Call Zeltiq Customer Service.
Temperature overshoot: Channel [].	Call Zeltiq Customer Service.
Temperature overshoot.	Call Zeltiq Customer Service.
Time-out while performing a security operation.	Remove the sleeve and install it again.
Treatment completed. []	
Treatment stopped.	
User cancelled treatment.	

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Appendix B: System Specifications

Contents

- “Environmental Requirements” on page B-1
- “Electrical Specifications” on page B-2
- “Medical Safety Standards” on page B-3
- “Electromagnetic Compatibility” on page B-3

This product may contain remanufactured parts or parts that have had incidental use, all of which are equivalent to new parts in performance.

Environmental Requirements

The system and its components are designed to operate normally when stored, shipped, and operated under the following conditions.

	<p>CAUTION: The Zeltiq System may not operate as expected if it is stored or operated in conditions of excessive heat, humidity, or atmospheric pressure. Operate and store the system in a room that meets the stated requirements. (Table B-1 on page B-1)</p>
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	Shipping / Storage	Operating
Temperature	32° F to 140° F (0° C - 60° C)	59° F to 82° F (15° C - 28° C)
Humidity	10% to 95% (non-condensing)	
Atmospheric Pressure	Sea level to 10,000 feet at standard pressure	

Table B-1: Shipping, Storage, and Operating Requirements

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Dimensions of the Control Unit and Modules

	Height	Depth	Width	Weight
Control unit alone	47-1/2 in	35 in	24 in	215 lbs
Control unit with support arm	62 in	n/a	n/a	216 lbs
Upper module	17 in	27-1/4 in	21-1/4 in	65 lbs
Base module	30-1/2 in	28-1/2 in	24 in	150 lbs

Table B-2: Control Unit - Dimensions

Electrical Specifications

Electrical Safety

Class I Equipment, single phase AC, Continuous Operation

Contains Type BF Patient-applied Parts

Water Ingress Protection: Ordinary Equipment, IPX0

REF	Voltage	Frequency	Current
BRZ-CG1-BAM-110	110-120VAC	50-60 Hz	13A
BRZ-CG1-BAM-220	220-240VAC	50-60 Hz	7A

Table B-3: Electrical Specifications

Fuses

The system contains two internal fuses: Type 3AB (ceramic cartridge), Rating: 250VAC, 6.25A, Slo-Blo. The fuses are not serviceable by the customer.

Medical Safety Standards

The system complies with the following medical safety standards:

IEC60601-1:1988+A2:1995

CAN/CSA C22.2 No 601.1-M90

UL60601-1:2003

AS/NZS 3200.1.0:1998

Electromagnetic Compatibility (EMC) IEC60601-1-2:2001+A1:2004 (Edition 2.1)

Electromagnetic Compatibility

The Zeltiq System (system) has been tested and found to comply with Medical Standard Electromagnetic Compatibility (EMC) IEC60601-1-2:2001+A1:2004 (Edition 2.1). The system complies with the standards outlined below.

This system requires special precautions to ensure electromagnetic compatibility with other electrical medical devices. To ensure EMC, the system must be installed and operated according to the information provided in this manual.

	<p>CAUTION: When the Zeltiq System is interconnected with other electrical devices, leakage currents may be additive, resulting in electromagnetic emissions that can interfere with the normal function of electronic medical equipment. To properly control electromagnetic emissions and avoid potential harm to the patient or user, ensure all electrical devices are installed and interconnected according to the requirements of IEC 60601-1-1.</p>
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	CAUTION: Install the Zeltiq System in a room that complies with all applicable IEC, CEC, and NEC requirements for safety of electrical devices.
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	CAUTION: Portable and mobile RF communications equipment may affect the normal function of the Zeltiq System.
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	CAUTION: Use of the Zeltiq System adjacent to or stacked with other equipment may result in unexpected electromagnetic circumstances. Prior to such use, test the operation of the Zeltiq System in the proposed configuration and ensure it meets all requirements as defined in the tables below. Consult the tables below for guidance in placing the system.
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	CAUTION: Use ports on the system exactly as instructed in this manual. Any other use of these ports may cause unexpected results. See "System Overview" on page 1-1.
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	<p>CAUTION: Do not use cables or accessories other than those provided by Zeltiq Aesthetics. The use of other cables or accessories may result in increased electromagnetic emissions or decreased immunity to such emissions.</p>
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Guidance and Manufacturer's Declaration -- Electromagnetic Emissions		
The Zeltiq System is intended for use in the electromagnetic environment specified below. The customer or user of the Zeltiq System should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Zeltiq System uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	(A) The Zeltiq System is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning statement is headed: CAUTION: The Zeltiq System is intended for use by healthcare professionals only. The Zeltiq System may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the Zeltiq System or shielding the location.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Class A	

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Guidance and Manufacturer's Declaration -- Electromagnetic Immunity			
The Zeltiq System is intended for use in the electromagnetic environment specified below. The customer or user of the Zeltiq System should ensure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±2,4,6kV contact ±2,4,8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for line to ground ±1kV for line to line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1kV differential mode ±2kV common mode	± 0.5, 1kV differential mode ±0.5, 1, 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Zeltiq System requires continued operation during power mains interruptions, it is recommended that the Zeltiq System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	n/a	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration -- Electromagnetic Immunity			
The Zeltiq System is intended for use in the electromagnetic environment specified below. The customer or user of the Zeltiq System should ensure that it is used in such an environment.			
Immunity Test	IEC60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Zeltiq System, including its cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80MHz	3 V	$d = 1.17\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz MHz	3 V/m	$d = 1, 2\sqrt{P}$ 80 mHz to 800 MHz $d = 2, 3\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by the electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. (a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zeltiq System is used exceeds the applicable RF compliance level above, the Zeltiq System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Zeltiq System. (b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Zeltiq System			
The Zeltiq System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The the user of the Zeltiq System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zeltiq System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power (W) of transmitter	Separation distance (m) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.17 P$	150 kHz to 80 MHz $d = 1.17 P$	800 MHz to 2.5 GHz $d = 2.23 P$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

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Attachment 2: DR-11071, COM1 Software Requirements Specification

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(b) (5) (b)(5)

COM1:DIS:161

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- **COM1:SRS:152** Deleted
- **COM1:SRS:153** Deleted

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Attachment 3: PL-11837 (AcuCool Vacuum Sleeve DFU) and PL-11822
(AcuCool Belt Sleeve)



**AcuCool Belt Sleeve
Directions for Use**

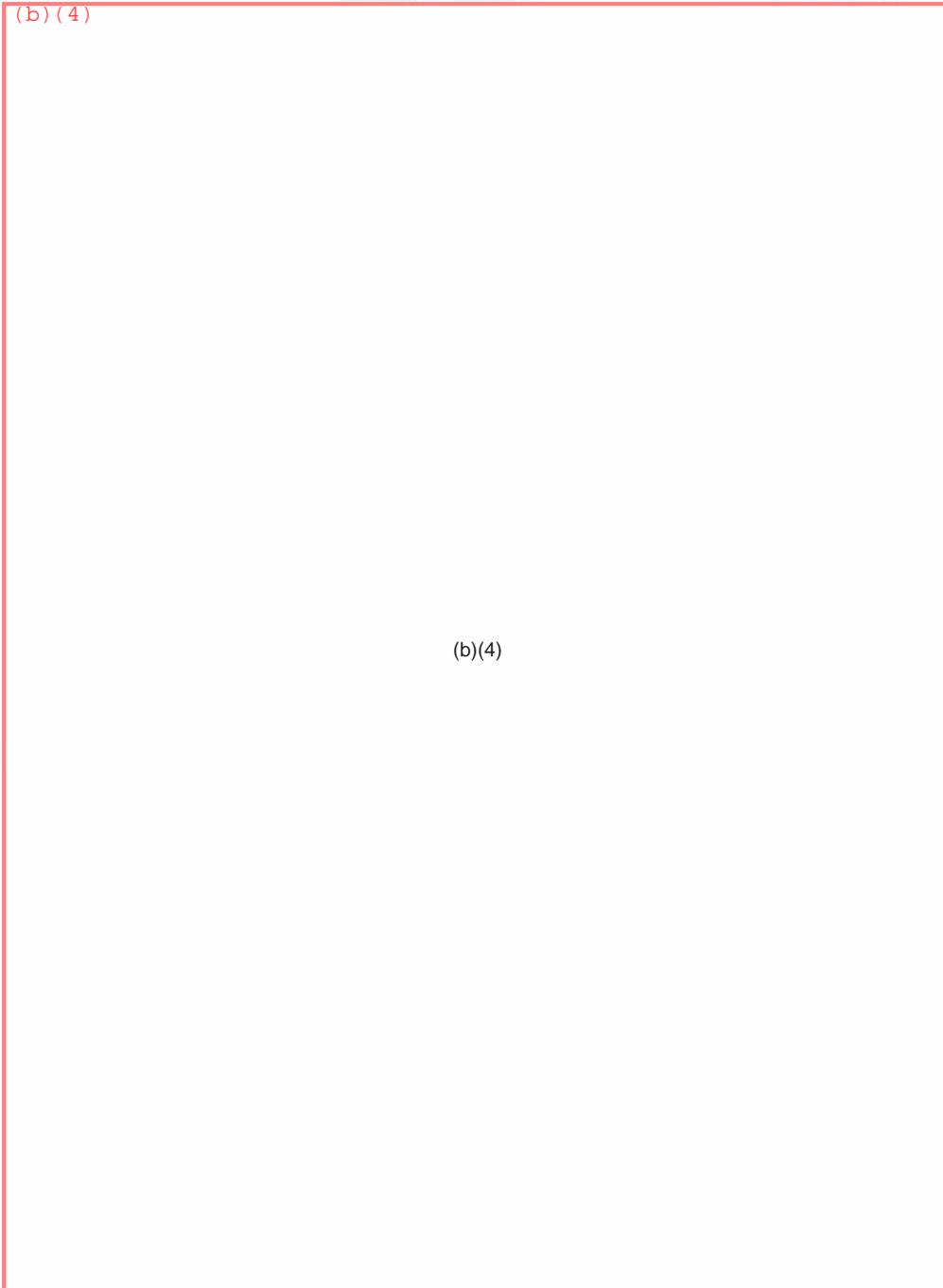
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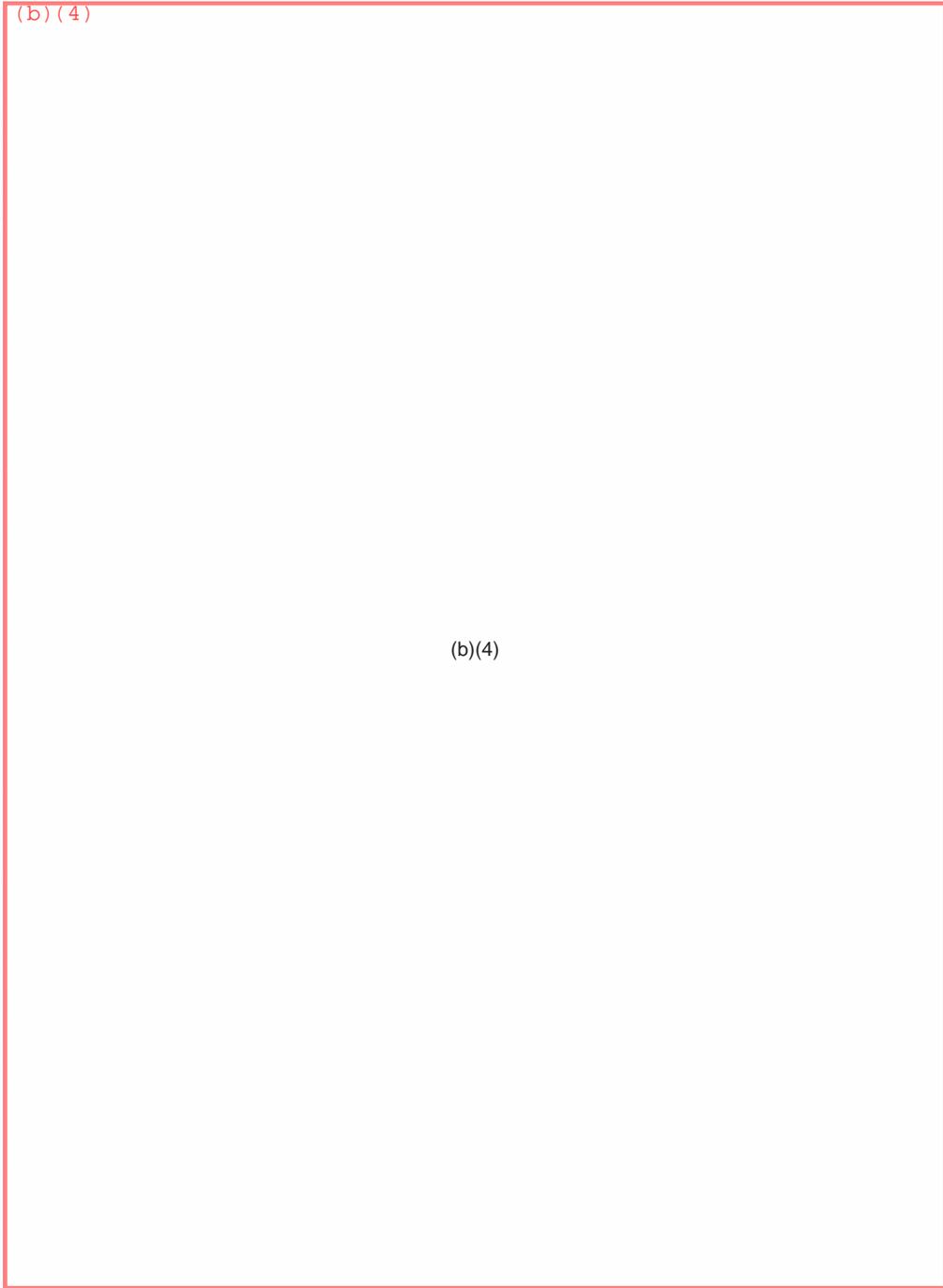
AcuCool Vacuum Sleeve
Directions for Use

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**Attachment 4: TR-177, COM1 SW Verification Results, SW Release 03.6
Report**

**Report, SW Verification Results, SW Release 03.6,
COM1
TR-177**

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Step #	Test Procedure	Expected Results	Actual Results	Pass/ Fail	Date of Execution (mm/dd/yy)
(b) (4)	(b) (4)	(b)(4)	(b)(4)		
	(b) (4)	(b)(4)			
(b) (4)	(b)(4)				
(b) (4)	(b) (4)	(b)(4)			

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Revision: 1

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Title: Report, SW Verification Results, SW Release 03.6, COM1

Step #	Test Procedure	Expected Results	Actual Results	Pass/ Fail	Date of Execution (mm/dd/yy)
(b)(4)					

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Step #	Test Procedure	Expected Results	Actual Results	Pass/ Fail	Date of Execution (mm/dd/yy)
(b) (4)			(b)(4)		

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