



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (jsh)
FOLDER: K082367 - 178 pages
COMPANY: LIFE INNOVATIONS LLC (LIFEINNOA)
PRODUCT: HOLDER, INFANT POSITION (FRP)
SUMMARY: Product: INFANT SLEEP BEANIE

DATE REQUESTED: Sep 10, 2015

DATE PRINTED: Sep 10, 2015

Note: Printed



Life Innovations
Limited Liability Company

510(k) SUMMARY

JUN 12 2009

Submitter: Life Innovations, LLC.
Address: P.O. Box 148
Wellington, CO 80549
Phone Number: (208) 316-5297
Fax Number: (208) 734-9941
Contact Person: Jane Y. Scott, M.D.
Chief Executive Officer
Jsc0704@aol.com

Date Prepared: June 10, 2009

Device Trade or Proprietary Name: Infant Sleep Beanie
Device Common or Usual Name: Pediatric position holder

Classification: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Panel: General Hospital and Personal Use Devices
Classification: Class I (reserved)
Classification Code: FRP

Predicate Device(s):

Kozy Comfort™ Infant Positioner	K062143
Head Bed™ Infant Positioner	K060986
Robin Hood Vest™	K051300
Nightform™ Infant Sleep Positioner	K041996

Device Description: The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.

Intended Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Technological Characteristics: The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled.

Performance Summary: The FDA has not established special controls or standards for this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Jane Y. Scott, M.D.
Chief Executive Officer
Life Innovations, LLC
P.O. Box 148
Wellington, Colorado 80549

Re: K082367
Trade/Device Name: Infant Sleep Beanie
Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: June 10, 2009
Received: June 10, 2009

Dear Dr. Scott:

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

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

Page 2- Dr. Scott

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 go to [http://www.fda.gov/AboutFDA/Centers Offices/CDRH/CDRHOffices/ucm115809.htm](http://www.fda.gov/AboutFDA/Centers%20Offices/CDRH/CDRHOffices/ucm115809.htm) for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Anthony D. ...
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

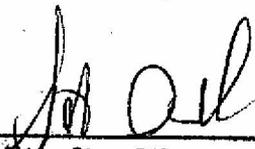
Prescription Use _____
(Part 21 CFR §801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082367

Life Innovations, LLC
Revised February, 2009



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

Janè Y. Scott, M.D.
Chief Executive Officer
Life Innovations, LLC
P.O. Box 148
Wellington, Colorado 80549

Re: K082367
Trade/Device Name: Infant Sleep Beanie
Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric Position Holder
Regulatory Class: I
Product Code: FRP
Dated: June 10, 2009
Received: June 10, 2009

Dear Dr. Scott:

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

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

Page 2- Dr. Scott

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 go to http://www.fda.gov/AboutFDA/Centers_Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

Anthony D. Mattar for
Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Prescription Use _____
(Part 21 CFR §801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082367

Life Innovations, LLC
Revised February, 2009



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 18, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 07, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

Extended Until: 06/09/2009

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

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

Life Innovations
Limited Liability Company

K082367

April 29, 2009

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

SUBJECT: 510(k) Premarket Notification K082367
Request for Extension of Time to Respond
to AI Request

Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On April 14, 2009 we received a letter from your office informing Life Innovations, LLC that review of the application is on hold for 30 days pending receipt of the additional information "AI" that was requested by the Office of Device Evaluation.

Life Innovations, LLC hereby requests an extension of the "hold" time in order to prepare our response for additional information.

I would appreciate hearing from you regarding this request for an extension of time at your earliest convenience.

Very truly yours,

Life Innovations, LLC
Signed:



Julianne Heath
Chief Financial Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jseo704@aol.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 14, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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(I)). 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.

50

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

March 17, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

96



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

January 27, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

Extended Until: 03/02/2009

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

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

*Life Innovations
Limited Liability Company*

January 21, 2009

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

SUBJECT: 510(k) Premarket Notification K082367
Request for Extension of Time to Respond
to AI Request

Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On December 30, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application is on hold for 30 days pending receipt of the additional information "AI" that was requested by the Office of Device Evaluation.

Life Innovations, LLC hereby requests an extension of the "hold" time in order to prepare our response for additional information.

I would appreciate hearing from you regarding this request for an extension of time at your earliest convenience.

Very truly yours,

Life Innovations, LLC

Signed:



Julianne Heath
Chief Financial Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jseo704@aol.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 30, 2008

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367
Product: INFANT SLEEP BEANIE
Extended Until: 01/30/2009

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

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

*Life Innovations
Limited Liability Company*

December 12, 2008

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

Received

DEC 30 2008

FDA CDRH L1C

SUBJECT: 510(k) Premarket Notification K082367
Request for Additional Extension of Time to
Respond to AI Request
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application is on hold for 30 days pending receipt of the additional information "AI" that was requested by the Office of Device Evaluation. On November 21, 2008 we received a 30-day extension of time to provide the additional information.

Life Innovations, LLC hereby requests another 30 day extension of the "hold" time in order to prepare our response for additional information.

I would appreciate hearing from you regarding this request for an extension of time at your earliest convenience.

Very truly yours,

Life Innovations, LLC
Signed:



Julianne Heath
Chief Financial Officer

129

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jsc0704@aol.com



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 21, 2008

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

Extended Until: 12/21/2008

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

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). 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.

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

133

K082367

**Life Innovations
Limited Liability Company**

November 18, 2008

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

FDA CDRH DMC

SUBJECT: 510(k) Premarket Notification K082367
Request for Extension of Time to Respond
to AI Request
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

NOV 20 2008

Received

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application is on hold for 30 days pending receipt of the additional information "AI" that was requested by the Office of Device Evaluation.

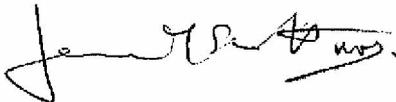
Life Innovations, LLC hereby requests an extension of the "hold" time in order to prepare our response for additional information.

I would appreciate hearing from you regarding this request for an extension of time at your earliest convenience.

Very truly yours,

Life Innovations, LLC

Signed:



Jane Scott
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: JSCO704@aol.com

K45



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

November 07, 2008

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 12, 2008

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-40)
9200 Corporate Blvd.
Rockville, Maryland 20850

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, CO 80549
ATTN: JANE SCOTT

510(k) Number: K082367
Received: 12-SEP-2008
Product: INFANT SLEEP BEANIE

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) need 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 electron copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsup.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
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

August 18, 2008

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, CO 80549
ATTN: JANE SCOTT

510(k) Number: K082367
Received: 18-AUG-2008
User Fee ID Number:
Product: INFANT SLEEP BEANIE

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. Please send a check to one of the addresses listed below:

By Regular Mail

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

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

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/electsub.html.

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 Christina Zeender at Christina.Zeender@fda.hhs.gov. 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
Office of Device Evaluation
Center for Devices and
Radiological Health

Life Innovations **K082367**
Limited Liability Company

FDA CDRH DMC

DATE: August 15, 2008 AUG 18 2008
ATTENTION: Office of Device Evaluation Received
Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850
SUBJECT: 510(k) PREMARKET NOTIFICATION

Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

ODE Division: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices

Panel: General Hospital and Personal Use Devices

Regulation Number: 21 CFR §880.5680

Regulation Name: Pediatric position holder

Regulatory Class: Class I (reserved)

Classification Code: FRP

K33

**Life Innovations, LLC
Infant Sleep Beanie
510(k) Premarket Notification**

TABLE OF CONTENTS

<u>510(k) Elements & Organization</u>	<u>Location in the Premarket Notification</u>
510(k) Cover Letter and Information Required by 21CFR§807.87	Pages 1 through 5
Predicate Device Information	Cover Letter page 3
Indications for Use Statement	Page 6
“Truthful and Accurate” Statement	Page 7
Description of the Device	Cover Letter page 2
Product Labeling	APPENDIX A – DRAFT LABELING
510(k) Summary	APPENDIX B – 510(k) SUMMARY
ClinicalTrials.gov Data Bank Certification (Form FDA 3674)	APPENDIX C – FDA Form 3674

Life Innovations
Limited Liability Company

August 15, 2008

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

SUBJECT: 510(k) Premarket Notification [21 *CFR* §807.90(e)]
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

ODE Division: Division of Anesthesiology, General Hospital, Infection Control and Dental
Devices
Panel: General Hospital and Personal Use Devices
Regulation Number: 21 *CFR* §880.5680
Regulation Name: Pediatric position holder
Regulatory Class: Class I (reserved)
Classification Code: FRP

Dear Sir or Madam:

Life Innovations, LLC hereby advises you that upon satisfactory completion of the review of this 510(k) Premarket Notification, Life Innovations, LLC intends to begin the introduction into interstate commerce for commercial distribution of the Infant Sleep Beanie.

Pursuant to 21 *CFR* §807.87, we are providing the following information pertaining to the Infant Sleep Beanie:

[§807.87(a)] Common Name of the Device:

Infant Position Holder

[§807.87(a)] Trade Name of the Device:

Infant Sleep Beanie

[§807.87(b)] Establishment Registration Number:

Life Innovations, LLC intends to complete the establishment registration and listing process within 30 days subsequent to the clearance of this Premarket Notification.

Life Innovations, LLC
510(k) Premarket Notification
Cover Letter -- page 1 of 5

[§807.87(c)] Classification of the Device:

21 *CFR* §880.5680: An Infant Position Holder is classified as a Class I (reserved) medical device. The device is GMP exempt.

[§807.87(d)] Actions taken to comply with Section 514 of the *FD&C* Act:

Section 514 of the *FD&C* Act does not apply to Class I medical devices.

[§807.87(e)] Representative labels, labeling and advertisements:

Attached in the Appendix A to this submission (LABELING) is a draft copy of the labeling for the Life Innovations Infant Sleep Beanie.

Description of the device:

The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel. The Infant Sleep Beanie is used to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to multiple different positions as needed with the use of a support roll stitched directly into the seam of the hat. The hat does not allow the infant to roll or turn away from the repositioning aid. Repositional therapy is most effective when the infant's head is placed to either side and to the back (right, back and to the left) daily. It is recommended that the infant's head be put into a new position after each use.

The Infant Sleep Beanie comes in several sizes to accommodate a baby's growing head size. It is made of a cotton blend material that is comfortable and easily washable. It is attractive and is available in several different fun designs and colors. The Infant Sleep Beanie is an easy device to use and could be considered a parent aid.

Intended use of the device:

Positional plagiocephaly is defined as the asymmetry of the skull shape resulting from birthing issues, pregnancy problems, congenital abnormalities and the common positional deformation (flat head). This problem results when infants are lying supported in the same position for prolonged periods of time. The incidence of the problem now varies from 13% up to an astounding 50% in twins.⁽¹⁾ Positional plagiocephaly typically occurs within the first few months of life, but a lifelong problem of skull deformity can result. Current medical thinking is that the problem has largely evolved out of two lifestyle changes:

1. Infants are being placed in carriers, car seats, swings, etc. for prolonged periods.
2. The 1992 American Academy of Pediatrics (AAP) recommendations for the "Back to Sleep" program.⁽²⁾

Once positional plagiocephaly has been diagnosed, most physicians recommend repositional therapy. Repositional therapy involves positioning the infant in a way to avoid putting pressure on the flattened areas. The therapy is most likely to be successful when done prior to six months

of age. If repositional therapy does not correct the problem, a physician may recommend cranial orthotic therapy. Cranial orthotic therapy involves the child wearing a custom-fitted headgear/helmet. The alternatives to repositional therapy are expensive and cannot guarantee a successful result. Helmets can be uncomfortable, unattractive to parents, and a last resort for the most severe cases. ⁽³⁾⁽⁴⁾⁽⁵⁾⁽⁶⁾⁽⁷⁾

The Life Innovations Infant Sleep Beanie is a first line repositioning aid for the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. Its function is to deflect the infant's head to desirable positions while lying asleep or awake. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

[§807.87(f)] Substantial equivalence of the Life Innovations Infant Sleep Beanie to a Predicate Device(s):

The Life Innovations Infant Sleep Beanie is substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to the following cleared infant position holders:

DEVICE	510(k) #	INTENDED USE	Type
Infant Sleep Beanie	TBD	<i>For healthy infants 0-9 months to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly.</i>	garment
Kozy Comfort™ Infant Positioner	K062143	<i>For healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.</i>	not specified
Head Bed™ Infant Positioner	K060986	<i>For infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.</i>	foam cushion
Robin Hood Vest™	K051300	<i>For use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.</i>	garment
Nightform™ Infant Sleep Positioner	K041996	<i>For healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.</i>	mattress

The Infant Sleep Beanie differs from the predicate infant position holders in that it is a hat that can be worn by the infant when asleep or awake.

[§807.87(g)] Information pertaining to a significant change to a device:

Not applicable. This is an original submission.

[§807.87(h)] 510(k) Summary:

In accordance with the requirements of 21 *CFR* §807.92, a "510(k) Summary" for the Life Innovations Infant Sleep Beanie is provided in the Appendix B to this notification [510(k) SUMMARY].

[§807.87(i)] Financial certification and/or disclosure statement:

This 510(k) Premarket Notification does not include clinical data and/or covered studies. Therefore, this Premarket Notification does not contain financial information pursuant to 21CFR Part 54. (Ref: FDA Guidance: Financial Disclosure by Clinical Investigators. Section IV; Q19)

[§807.87(j)] Statements regarding substantial equivalence to a Class III device:

Not applicable to this device.

[§807.87(k)] Truth and Accuracy Statement:

A statement of truth and accuracy is attached.

[§807.87(l)] Additional information:

Medical Device User Fee (Form FDA 3601):

This 510(k) Premarket Notification is for a medical device intended solely for a pediatric population. Per the Medical Device User Fee and Modernization Act of 2002, a medical device user fee is not required.

Indications for Use Statement:

An "Indications for Use" statement is attached.

ClinicalTrials.gov Data Bank (Form FDA 3674):

A completed Form 3674 is provided in the Appendix to this notification (FDA FORM 3674).

Supporting References:

(b)(4)



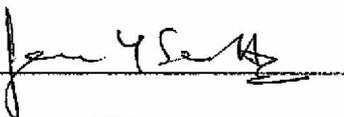
Conclusion:

It is respectfully submitted that the Life Innovations Infant Sleep Beanie is substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to a predicate device(s) which is in commercial distribution in interstate commerce.

I would appreciate hearing from you regarding this Premarket Notification at your earliest convenience.

Very truly yours,

Life Innovations, LLC
Signed:



Jane Scott
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 420-5059
Fax: (208) 734-9941
Email: Jsc0704@aol.com

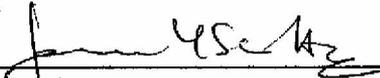
510(k) PREMARKET NOTIFICATION

**Life Innovations, LLC
INFANT SLEEP BEANIE**

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21CFR§807.87(k)]

I certify that, in my capacity as Chief Executive Officer of Life Innovations, LLC I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Jane Scott

Date: 8/16/08

Life Innovations
Limited Liability Company

APPENDIX A - LABELING

DRAFT LABELING

**LIFE INNOVATIONS, LLC
INFANT SLEEP BEANIE**

Labeling On Product:

**FRONT:
Infant Sleep Beanie**

**By Life Innovations, LLC
Wellington, CO**

LOT#

**All New Material
95% Cotton/5% Spandex
Exclusive of decoration**

Care on Reverse

Sizing:

Age: (b)(4), Draft

Weight:

Made in

Distributed by

BACK:

CARE INSTRUCTIONS:

Machine wash cold with like colors. Do not bleach. Tumble dry low heat.

DIRECTIONS FOR USE:

Infant Sleep Beanie is an aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. Infant Sleep Beanie is intended for healthy infants from 0-9 months. Its purpose is to deflect the infants' head gently to desirable positions while lying asleep or awake.

Infant Sleep Beanie should be placed directly on infant's head while lying awake, sleeping or during travel. The hat will aid in repositioning the head

Life Innovations, LLC
510(k) Premarket Notification
Appendix A -- Labeling
Page 1

167

to multiple different positions as needed with the use of a support roll stitched directly into the seam of the hat.

Change the position of the support roll by adjusting the hat appropriately on infant's head to either side and to the back. Repositioning is most effective when the infant's head is placed into several positions (right, back and to the left) daily. It is recommended that the infant's head be put into a new position after each use.

[ILLUSTRATION]

FREQUENTLY ASKED QUESTIONS:

What is positional plagiocephaly?

Positional plagiocephaly is defined as the asymmetry of the skull shape resulting from birthing issues, pregnancy problems, congenital abnormalities and the common positional deformation (flat head). This problem results when young infants are lying supported in the same position for prolonged periods of time. This condition typically occurs within the first few months of life.

What is repositional therapy?

Once positional plagiocephaly has been diagnosed, most physicians recommend repositional therapy. Repositional therapy involves positioning the child in a way to avoid putting pressure on the flattened areas. This kind of therapy is most likely to be successful when done prior to 6 months of age.

CONFIDENTIAL

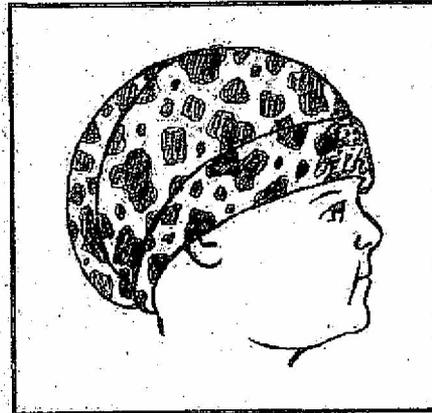
Life Innovations, LLC

Infant Sleep Beanie

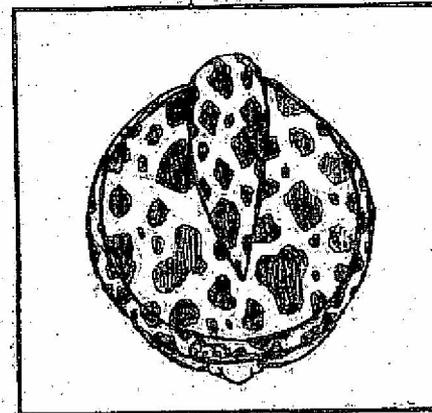
Front View



Side View



Top View



Life Innovations, LLC
510(k) Pre market Notification
Appendix A - Labeling
Page 3

Life Innovations
Limited Liability Company

APPENDIX B - 510(k) SUMMARY

Life Innovations
Limited Liability Company

510(k) SUMMARY

Submitter: Life Innovations, LLC.
Address: P.O. Box 148
Wellington, CO 80549
Phone Number: (208) 420-5059
Fax Number: (208) 734-9941
Contact Person: Jane Scott
Chief Executive Officer
Jsc0704@aol.com

Date Prepared: August 15, 2008

Device Trade or Proprietary Name: Infant Sleep Beanie
Device Common or Usual Name: Pediatric position holder

Classification: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Panel: General Hospital and Personal Use Devices
Classification: Class I (reserved)
Classification Code: FRP

Predicate Device(s):

Kozy Comfort™ Infant Positioner	K062143
Head Bed™ Infant Positioner	K060986
Robin Hood Vest™	K051300
Nightform™ Infant Sleep Positioner	K041996

Device Description: The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.

Intended Use: The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months. Its purpose is to deflect the infant's head gently to desirable positions while lying asleep or awake.

Technological Characteristics: The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled. The Life Innovations Infant Sleep Beanie comes in multiple colors and designs to coordinate with infant clothing.

Performance Summary: The FDA has not established special controls or standards for this device.

Indications for Use

510(k) Number (if known):

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Prescription Use _____
(Part 21 CFR §801 Subpart D)

AND/OR

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

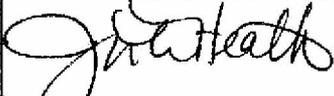
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Life Innovations, LLC
510(k) Premarket Notification
Page 6

Life Innovations
Limited Liability Company

APPENDIX C - FDA FORM 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		
1. NAME OF SPONSOR/APPLICANT/SUBMITTER Life Innovations, LLC	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 08/15/2008	
3. ADDRESS (Number, Street, State, and ZIP Code) (b)(4) Wellington, CO 80549 PO Box 148, Wellington, CO 80549	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (208) 420-5059 (Fax) (208) 734-9941	
PRODUCT INFORMATION		
5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s) FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s) (Attach extra pages as necessary)		
Common or usual name: Infant position holder, Class I Tradename: Infant Sleep Beanie		
APPLICATION / SUBMISSION INFORMATION		
6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES <input type="checkbox"/> IND <input type="checkbox"/> NDA <input type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> PMA <input type="checkbox"/> HDE <input checked="" type="checkbox"/> 510(k) <input type="checkbox"/> PDP <input type="checkbox"/> Other		
7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)		
8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES		
CERTIFICATION STATEMENT INFORMATION		
9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)		
<input checked="" type="checkbox"/> A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.		
<input type="checkbox"/> B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.		
<input type="checkbox"/> C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.		
10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)		
NCT Number(s):		
The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willful and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.		
11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Julianne Heath (Title) Chief Financial Officer	
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) (b)(4), Wellington CO 80549	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) (b)(4), (b)(6) (Fax)	15. DATE OF CERTIFICATION 8/11/08



COVER SHEET MEMORANDUM

From: Reviewer Name LEUNG SHEN
Subject: 510(k) Number K082367/54
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%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	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
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 <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
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)			✓
Is this device intended for pediatric use only?		✓	⊗
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)		✓	
Infant (29 days - < 2 years old)	<u>to 9 months</u>	✓	
Child (2 years - < 12 years old)			✓
Adolescent (12 years - < 18 years old)			✓
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.)			✓

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years)		✓
nanotechnology		✓
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 **Class*** **Product Code**

880.5680

II I

FRP

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review:

M. All
(Branch Chief)

NO

(Branch Code)

6/10/09

(Date)

Final Review:

Anthony D. ... for MSA
(Division Director)

6/11/09

(Date)

5



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K082367 S004

Date: June 10, 2009

To: The Record

Office: HFZ-480

From: Lening Shen, General Engineer

Division: DAGID/GHDB

510(k) Holder: Life Innovations, LLC

Device Name: Infant Sleep Beanic

Classification: Class I 880.5680, FRP, Pediatric position holder

Contact: Jane Scott, CEO

Phone: 208-316-5297

Fax: 208-734-9941

Email: jsco704@aol.com

Address: P.O. Box 148, Wellington, CO 80549, USA

RECOMMENDATION: Substantially Equivalent → June 10, 2009

I. Purpose and Submission Summary

The purpose of this submission is to determine substantial equivalence with the following devices:

- K062143 Kozy Comfort™ Infant Positioner
- K060986 Head Bed™ Infant Positioner (foam cushion)
- K051300 Robin Hood Vest™ (Garment)
- K041996 Nightform™ Infant Sleep Positioner (mattress)

Reviewer's Note: The sponsor has provided enough information about the subject device and related predicate devices. -- Acceptable.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) - <i>Acceptable</i>	Y		
Truthful and Accuracy Statement - <i>Acceptable</i>	Y		

6



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

	Yes	No	N/A
510(k) Summary or 510(k) Statement – <i>Summary provided - Deficiency</i>	Y		
Standards Form – <i>None declared.</i>			X

Reviewer's Note: The sponsor has provided all documents listed above and met the administrative requirements. However, the IFU on the 510(k) Summary is not identical to the IFU statement. - Deficiency.

Reviewer's Note (06/10/2009): The sponsor has provided the revised 510(k) Summary that contains identical IFU statement as that of the IFU. – Acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile?		N	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user? – Not Applicable	Y		

Description of the Devices:

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

Reviewer's Note: The sponsor has provided a clear description of the device. It is essentially a hat that the infant wears during sleep or awake. The hat will prevent the infant from rolling or turning from the repositioning aid. - Acceptable.

IV. Indications for Use

Subject Device:

Revised (02/25/2009):

The Life Innovations Infant Sleep Beanie is an over the counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants from 0-9 months of age.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Original:

The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Predicate Device (K062143):

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly.

Predicate Device (K060986):

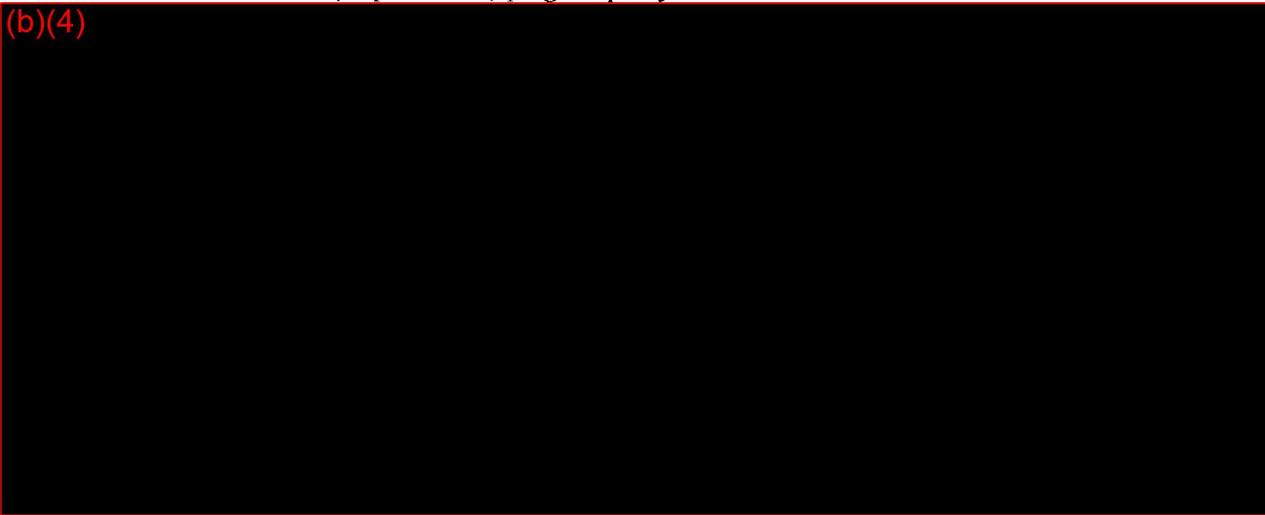
The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.

Predicate Device (K051300):

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

Predicate Device (K041996):

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.



V. Predicate Device Comparison

The sponsor has provided the following table of comparison between the device and its predicate:

Device	Type
--------	------



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Infant Sleep Beanie	Garment
Kozy Comfort Infant Positioner	Positioner
Head Bed Infant Positioner	Foam cushion
Robin Hood Vest	Garment
Nightform Infant Sleep Positioner	Mattress

Reviewer's Note: The sponsor provided predicate device information to establish that the subject devices are intended to be used for similar operations. --- Acceptable.

VI. Labeling

The sponsor has provided Size reference, Care Instructions, Directions for Use for the device.

(b)(4)

Reviewer's Note: the labeling is incomplete because it did not include the Indication for Use statement. - Deficiency.

Reviewer's Note (04/06/2008): The sponsor has inserted the Indication for Use statement in S002 of the submission. - Acceptable.

VII. Sterilization/Shelf Life/Reuse

The product is not supplied sterile. All predicate devices are supplied non-sterile. Therefore, it is acceptable.

The submission did not mention Shelf Life, therefore shelf life is not claimed.

The device is apparently reusable being it is a hat. Cleaning instructions are provided in the labeling section of the submission (b)(4)

(b)(4)

Reviewer's Note: - Adequate.

VIII. Biocompatibility

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



IX. Software

Not applicable. This device does not contain software - *Acceptable.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



XII. Performance Testing – Animal

Not applicable. - *Acceptable*

XIII. Performance Testing – Human Factors

Not applicable - *Acceptable.*

M



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

XIV. Substantial Equivalence Discussion (Substantially Equivalent – June 10, 2009)

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?	X		If NO = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
The sponsor needs to provide supporting evidence that the weight of the hat does not pose risk to the infants.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

The sponsor needs to complete the labeling section of the submission to add indications for use.

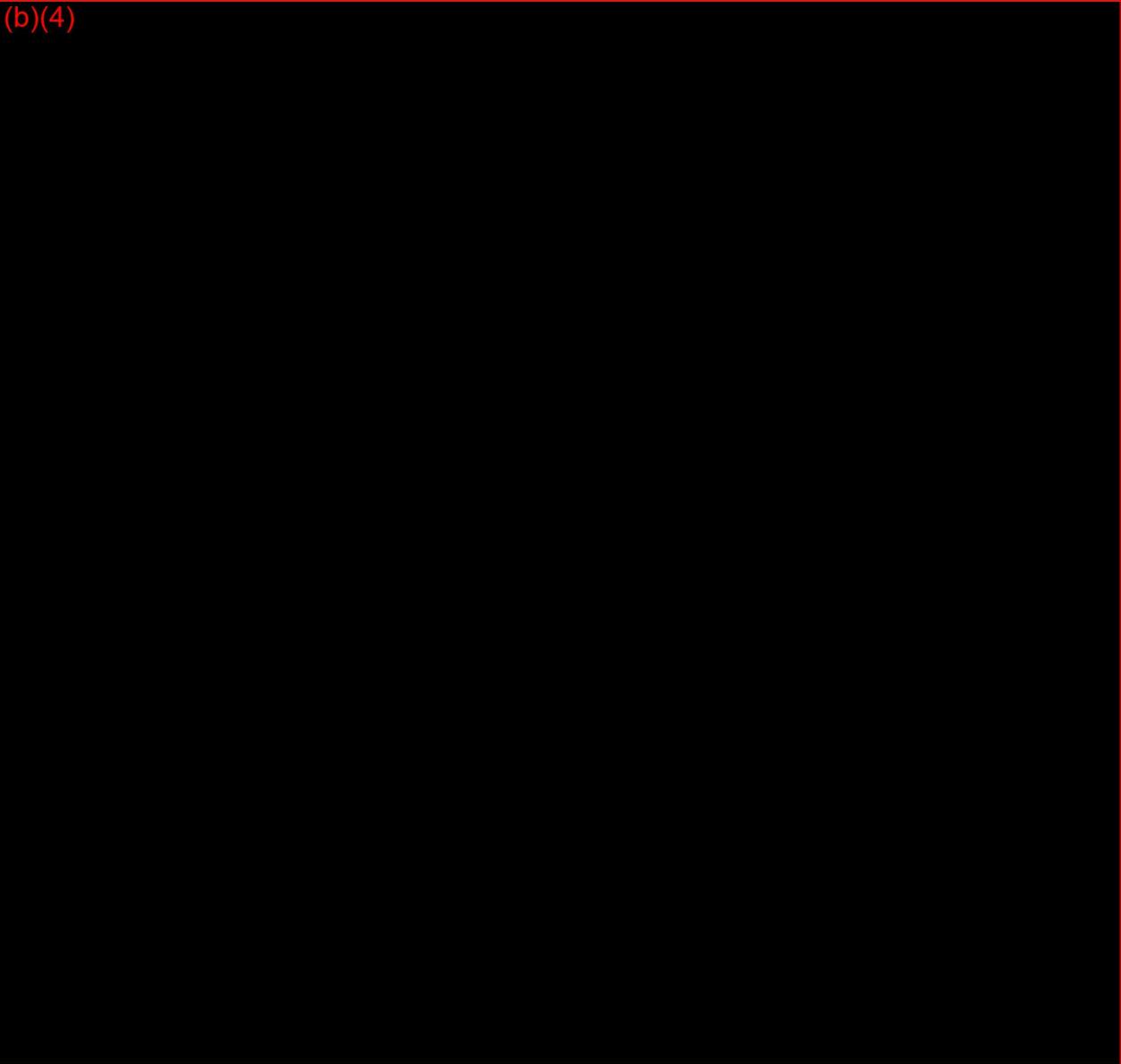
(b)(4)

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

XV. Deficiencies

We found the following deficiencies with the submission:

(b)(4)

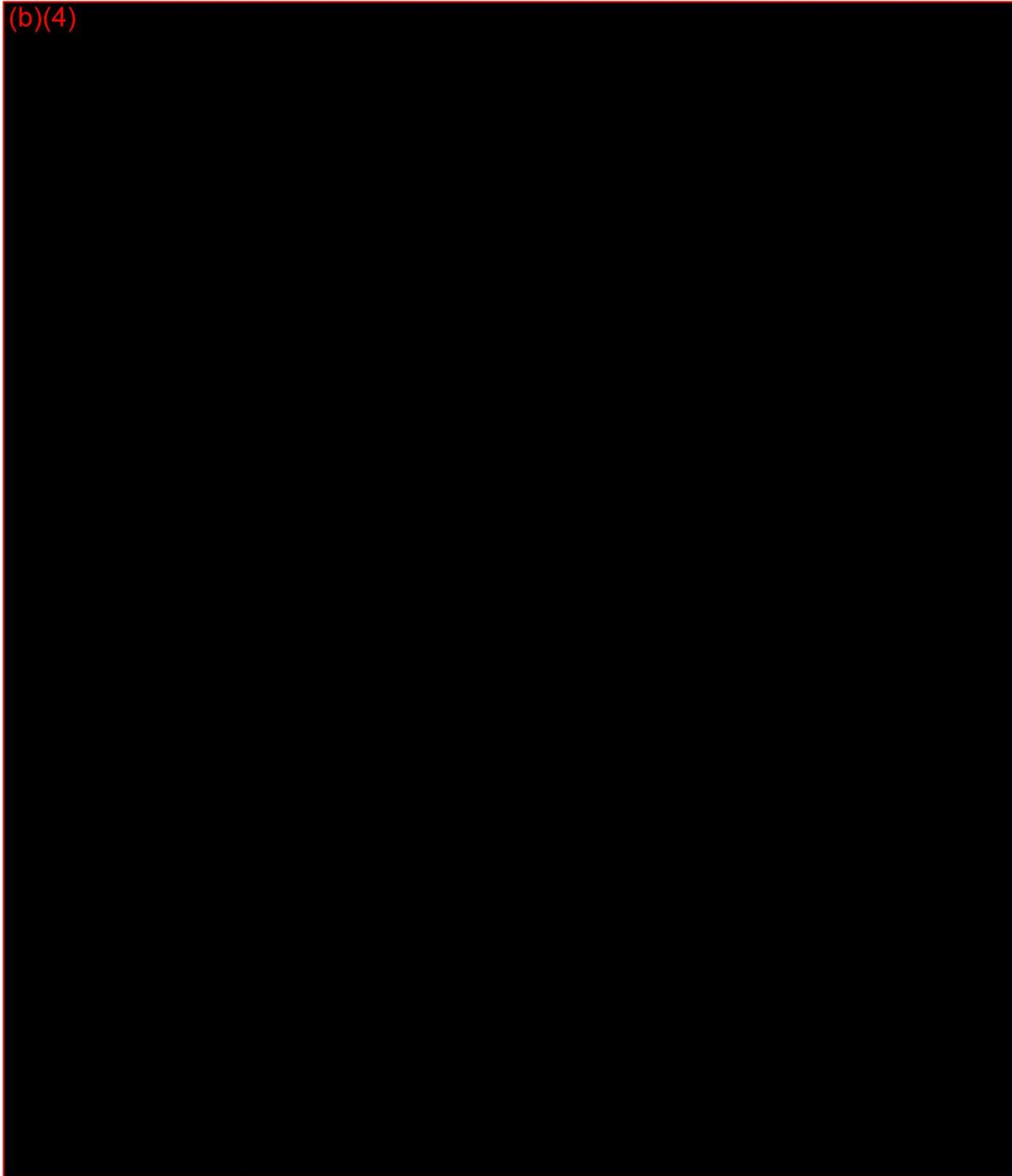




DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850



3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

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

Additional Deficiencies (S001)

1. The labeling you have provided in your submission is incomplete. You have not included the Indications for Use as a part of your labeling. Please clearly identify and insert the Indications for Use statement as part of your product Labeling. Please provide an update version of your product labeling.

Reviewer's Note (04/06/2009): The sponsor has responded by inserting the Indications for Use statement. – Acceptable.

(b)(4)

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



2. You have provided us with an updated 510(k) Summary. However, the Intended Use statement in the Summary and the Indications For Use statement are not identical. Please revise your Intended Use statement in 510(k) Summary to be identical to Indication For Use statement.

Reviewer's Note (06/10/2009): The sponsor have provided a revised 510(k) Summary that contains the same Intended Use as the Indications for Use statement. - Acceptable.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

XVI. Contact History

1. 03/03/2009. Called the sponsor request for updated IFU statement with "Over-the-Counter use" checked. Additionally, need the sponsor to update the 510(k) Summary to make the "Intended Use" section identical to the IFU statement.
2. 03/04/2009. Sponsor email me with the revised IFU statement and the 510(k) Summary.

XVII. Recommendation

Regulation Number: 21 CFR 880.5680
 Regulation Name: Pediatric position holder
 Regulatory Class: Class I
 Product Code: FRP

RECOMMENDATION: SE->June 10, 2009

Lsh

 Reviewer

6/10/09

 Date

[Signature]

 Branch Chief

6/10/09

 Date

Anthony D. ... for MSR

6/11/09



COVER SHEET MEMORANDUM

From: Reviewer Name LEWIS SHEN
Subject: 510(k) Number K082367/S3
To: The Record

Please list CTS decision code _____

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	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
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)			✓
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)			✓
Is this device intended for pediatric use only?		✓	
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
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.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)	to 9 months	✓	
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
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.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

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 OSE.
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	Class*	Product Code
880 7680	I	FRP
(*if unclassified, see 510(k) Staff)		

Additional Product Codes: _____

Review: _____
 (Branch Chief) 02/15/09 (Branch Code) _____ (Date) _____

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

Shen, Lening

From: Shen, Lening
Sent: Friday, May 15, 2009 3:18 PM
To: 'jsco704@aol.com'
Cc: Colburn, Scott A; Zimliki, Charles L* (CDRH)
Subject: 510(k) submission K082367/S002: Infant Sleep Beanie

Jane Scott, CEO
Life Innovations, LLC
P.O. Box 148
Wellington, CO 80549
jsco704@aol.com

Dear Ms. Scott,

We have reviewed your response to our April 10, 2009 email request for additional information regarding your 510(k) submission K082367: Infant Sleep Beanie. To complete the review of your submission, we request the following additional information:

1. You have provided a response for the (b)(4) 
(b)(4) 
2. You have provided us with an updated 510(k) Summary. However, the Intended Use statement in the Summary and the Indications For Use statement are not identical. Please revise your Intended Use statement in 510(k) Summary to be identical to Indication For Use statement.

Please confirm that you have received this e-mail. I am placing this submission on hold. All information you submit in response to this request should be send to our document control center as a supplement to this 510(k) (K082367) submission. If you have any questions, please contact me.

Sincerely,

Lening Shen
General Engineer
General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: (240) 276-3713
Fax: (240) 276-3789



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K082367 S003

Date: May 13, 2009

To: The Record

Office: HFZ-480

From: Lening Shen, General Engineer

Division: DAGID/GHDB

510(k) Holder: Life Innovations, LLC

Device Name: Infant Sleep Beanie

Classification: Class I 880.5680, FRP, Pediatric position holder

Contact: Jane Scott, CEO

Phone: 208-316-5297

Fax: 208-734-9941

Email: jsco704@aol.com

Address: P.O. Box 148, Wellington, CO 80549, USA

RECOMMENDATION: Telephone Hold → Additional Information May 13, 2009

I. Purpose and Submission Summary

The purpose of this submission is to determine substantial equivalence with the following devices:

- K062143 Kozy Comfort™ Infant Positioner
- K060986 Head Bed™ Infant Positioner (foam cushion)
- K051300 Robin Hood Vest™ (Garment)
- K041996 Nightform™ Infant Sleep Positioner (mattress)

Reviewer's Note: The sponsor has provided enough information about the subject device and related predicate devices. — Acceptable.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) - <i>Acceptable</i>	Y		
Truthful and Accuracy Statement - <i>Acceptable</i>	Y		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

	Yes	No	N/A
510(k) Summary or 510(k) Statement – <i>Summary provided - Deficiency</i>	Y		
Standards Form – <i>None declared.</i>			X

Reviewer's Note: The sponsor has provided all documents listed above and met the administrative requirements. However, the IFU on the 510(k) Summary is not identical to the IFU statement. - Deficiency.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile?		N	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user? – Not Applicable	Y		

Description of the Devices:

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

Reviewer's Note: The sponsor has provided a clear description of the device. It is essentially a hat that the infant wears during sleep or awake. The hat will prevent the infant from rolling or turning from the repositioning aid. - Acceptable.

IV. Indications for Use

Subject Device:

Revised (02/25/2009):

The Life Innovations Infant Sleep Beanie is an over the counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants from 0-9 months of age.

Original:



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Predicate Device (K062143):

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly.

Predicate Device (K060986):

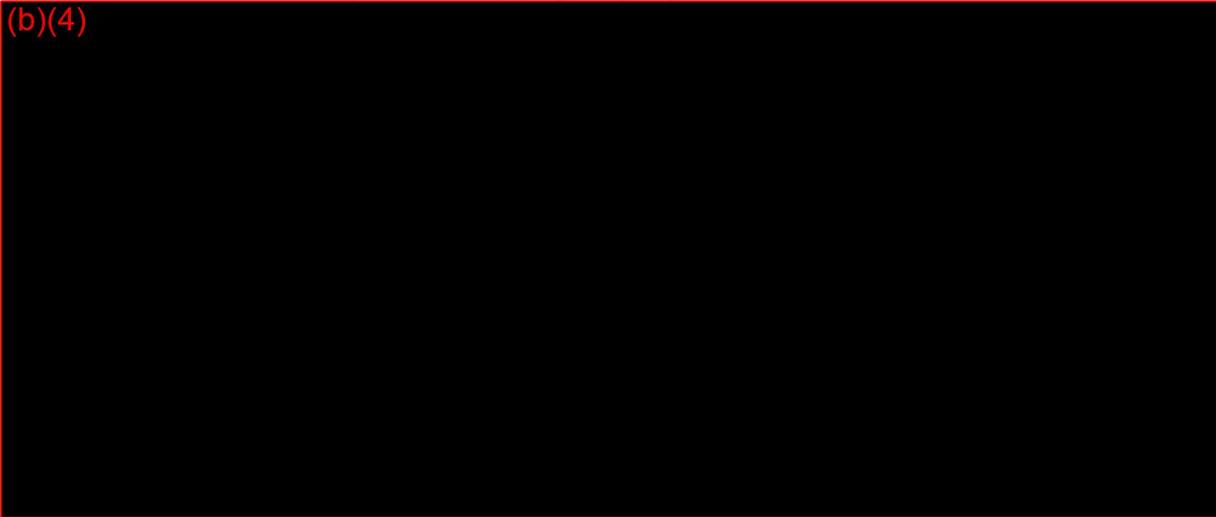
The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.

Predicate Device (K051300):

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

Predicate Device (K041996):

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.



V. Predicate Device Comparison

The sponsor has provided the following table of comparison between the device and its predicate:

Device	Type
Infant Sleep Beanie	Garment
Kozy Comfort Infant	Positioner



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Positioner	
Head Bed Infant Positioner	Foam cushion
Robin Hood Vest	Garment
Nightform Infant Sleep Positioner	Mattress

Reviewer's Note: The sponsor provided predicate device information to establish that the subject devices are intended to be used for similar operations. --- Acceptable.

VI. Labeling

The sponsor has provided Size reference, Care Instructions, Directions for Use for the device.

(b)(4)

Reviewer's Note: the labeling is incomplete because it did not include the Indication for Use statement. - Deficiency.

Reviewer's Note (04/06/2008): The sponsor has inserted the Indication for Use statement in S002 of the submission. - Acceptable.

VII. Sterilization/Shelf Life/Reuse

The product is not supplied sterile. All predicate devices are supplied non-sterile. Therefore, it is acceptable.

The submission did not mention Shelf Life, therefore shelf life is not claimed.

The device is apparently reusable being it is a hat. Cleaning instructions are provided in the labeling section of the submission (b)(4)

(b)(4)

Reviewer's Note: - Adequate.

VIII. Biocompatibility

(b)(4)

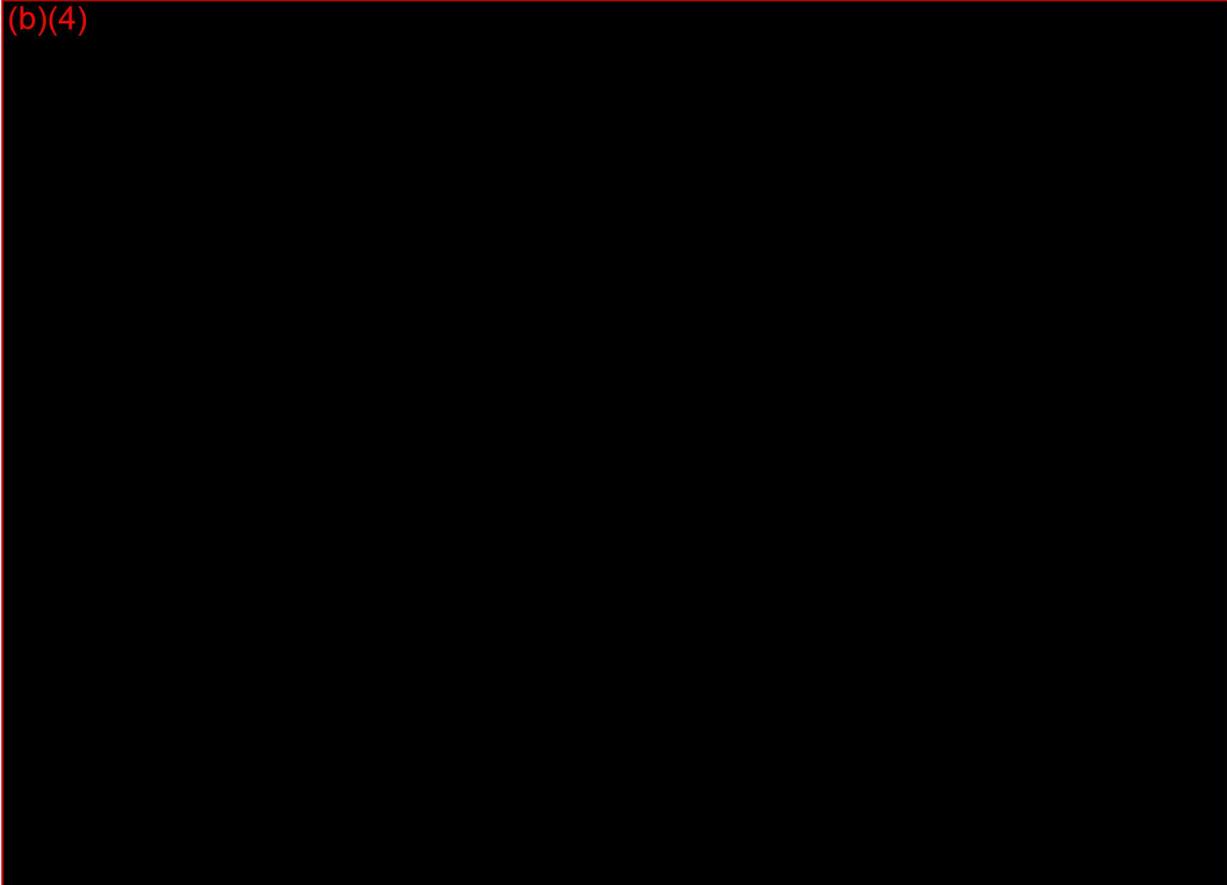


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



IX. Software

Not applicable. This device does not contain software - *Acceptable*.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4)

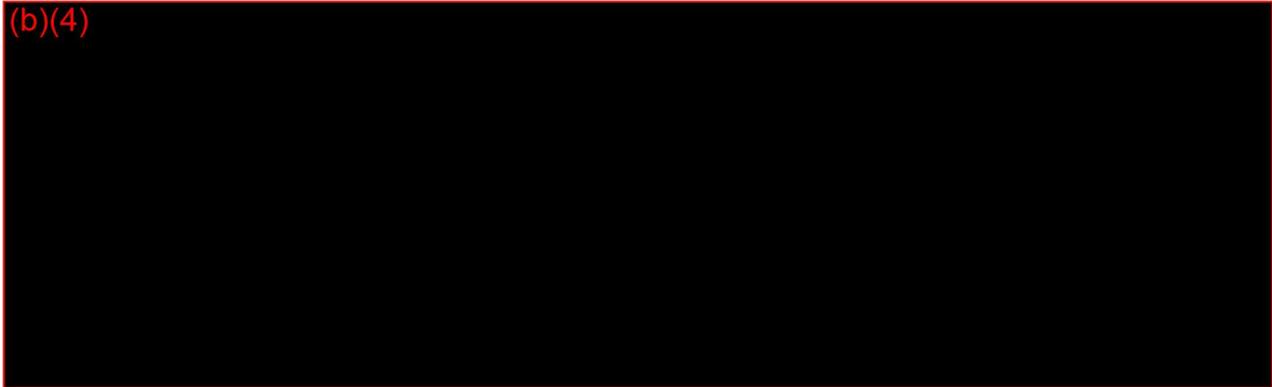




DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850



XII. Performance Testing – Animal

Not applicable. - *Acceptable*

XIII. Performance Testing – Human Factors

Not applicable - *Acceptable*.

XIV. Substantial Equivalence Discussion (Telephone Hold – May 15, 2009)

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:SE

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
The sponsor needs to provide supporting evidence that the weight of the hat does not pose risk to the infants.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
The sponsor needs to complete the labeling section of the submission to add indications for use.
(b)(4)
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

We found the following deficiencies with the submission:

(b)(4)

A large black rectangular redaction box covers the entire content of the deficiencies section, starting from the text "(b)(4)" and extending down to the bottom of the page.

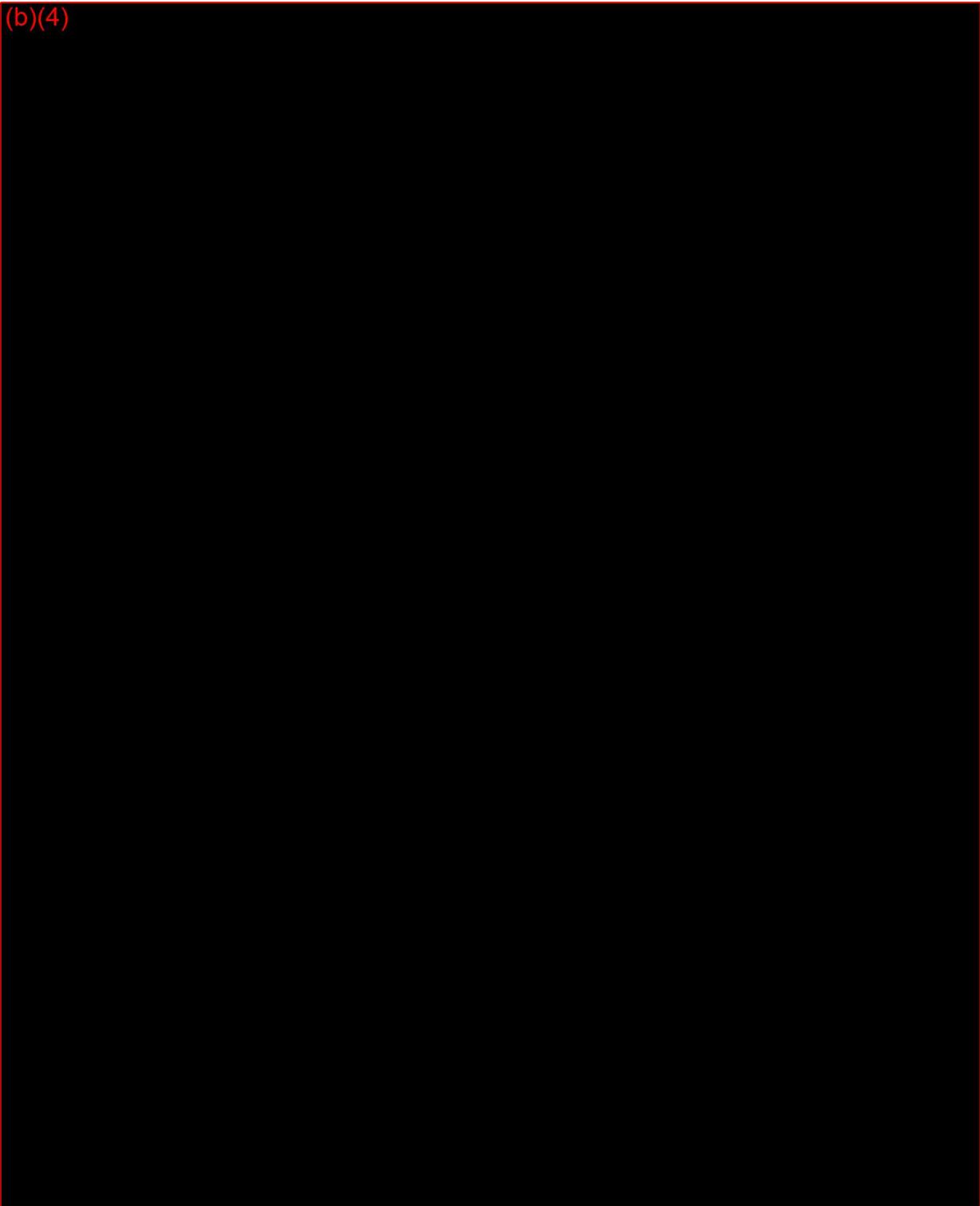


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

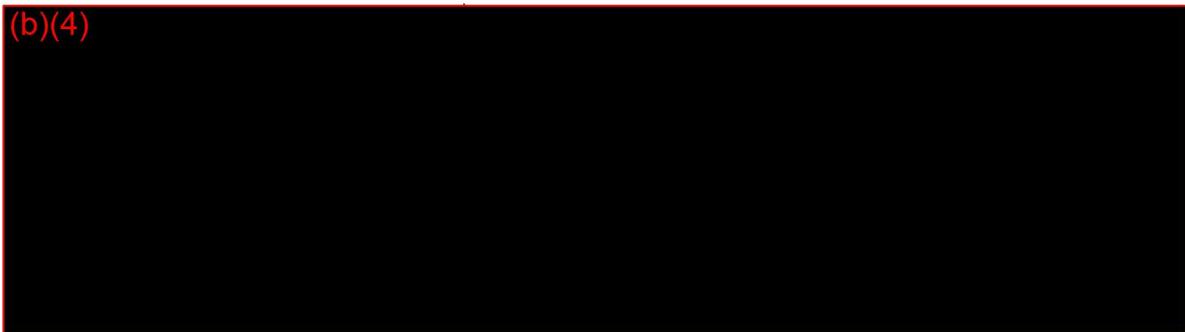
MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850



3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

Reviewer's Note (03/09/2009): The sponsor has responded by revising the labeling to include size suggestions. Dr. Joy Samuels-Reid reviewed this information and found them to be adequate. – Acceptable.



Additional Deficiencies (S001)

1. The labeling you have provided in your submission is incomplete. You have not included the Indications for Use as a part of your labeling. Please clearly identify and insert the Indications for Use statement as part of your product Labeling. Please provide an update version of your product labeling.



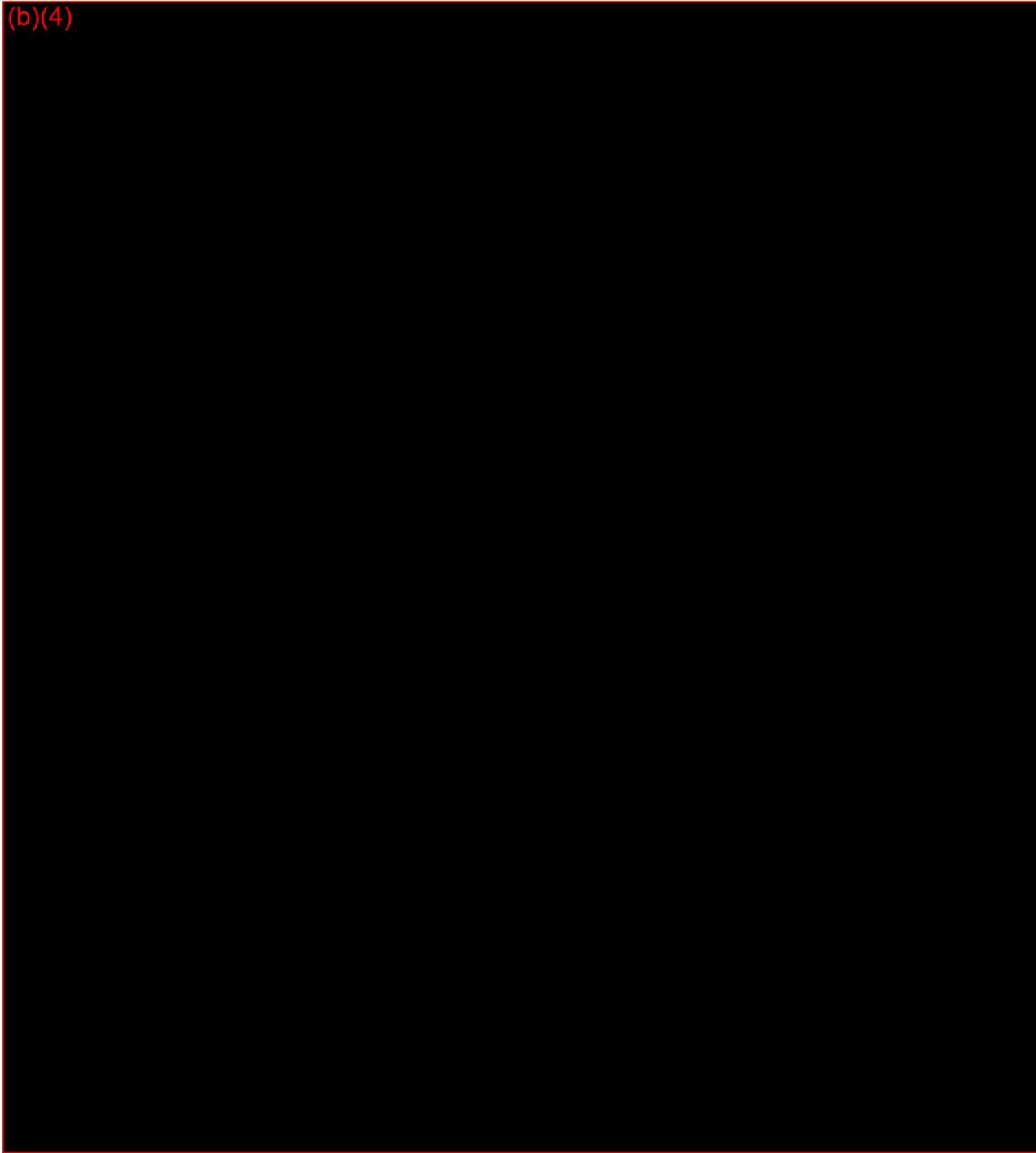
DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Reviewer's Note (04/06/2009): The sponsor has responded by inserting the Indications for Use statement. – Acceptable.

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850



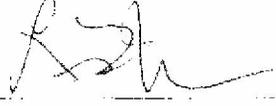
XVI. Contact History

1. 03/03/2009. Called the sponsor request for updated IFU statement with "Over-the-Counter use" checked. Additionally, need the sponsor to update the 510(k) Summary to make the "Intended Use" section identical to the IFU statement.
2. 03/04/2009. Sponsor email me with the revised IFU statement and the 510(k) Summary.

XVII. Recommendation

Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric position holder
Regulatory Class: Class I
Product Code: FRP

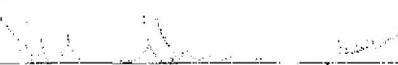
RECOMMENDATION: TII, May 15, 2009



Reviewer

5/15/09

Date



Branch Chief

5/15/09

Date

CE 5/15/09

**COVER SHEET MEMORANDUM**

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

JENING SHEN

K082367/52

Please list CTS decision code TX

- 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	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary /510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?			<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision		<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			<input checked="" type="checkbox"/>
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)			<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)			<input checked="" type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?			<input checked="" type="checkbox"/>
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.)			<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?			<input checked="" type="checkbox"/>
All Pediatric Patients age ≤ 21			<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)			<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)	<u>to 9 months</u>		<input checked="" type="checkbox"/>
Child (2 years - < 12 years old)			<input checked="" type="checkbox"/>
Adolescent (12 years - < 18 years old)			<input type="checkbox"/>
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.)			<input type="checkbox"/>
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			<input type="checkbox"/>
Nanotechnology			<input type="checkbox"/>

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 **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

Review: _____

(Branch Chief)

(Branch Code)

(Date)

Final Review: _____

(Division Director)

(Date)

Shen, Lening

From: Shen, Lening
Sent: Friday, April 10, 2009 11:53 AM
To: 'jsco704@aol.com'
Cc: Colburn, Scott A; Zimlik, Charles L* (CDRH)
Subject: 510(k) submission K082367/S002: Infant Sleep Beanie

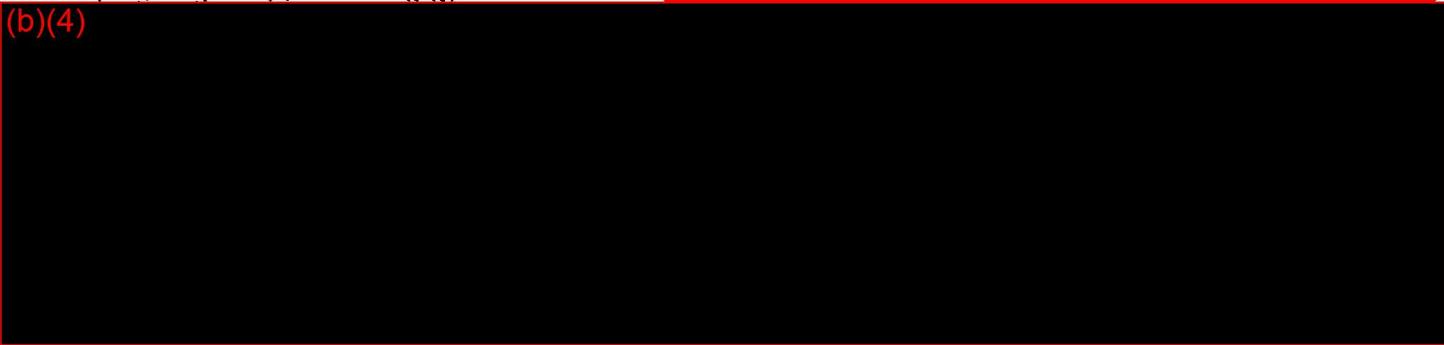
Jane Scott, CEO
Life Innovations, LLC
P.O. Box 148
Wellington, CO 80549
jsco704@aol.com

Dear Ms. Scott,

We have reviewed your response to our March 16, 2009 email request for additional information regarding your 510(k) submission K082367: Infant Sleep Beanie. To complete the review of your submission, we request the following additional information:

You have responded to the Agency's request for (b)(4)

(b)(4)



Please confirm that you have received this e-mail. I am placing this submission on hold. All information you submit in response to this request should be send to our document control center as a supplement to this 510(k) (K082367) submission. If you have any questions, please contact me.

Sincerely,

Lening Shen
General Engineer
General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: (240) 276-3713
Fax: (240) 276-3789



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K082367 S002

Date: April 9, 2009

To: The Record

Office: HFZ-480

From: Lening Shen, General Engineer

Division: DAGID/GHDB

510(k) Holder: Life Innovations, LLC

Device Name: Infant Sleep Beanie

Classification: Class I 880.5680, FRP, Pediatric position holder

Contact: Jane Scott, CEO

Phone: 208-316-5297

Fax: 208-734-9941

Email: jsco704@aol.com

Address: P.O. Box 148, Wellington, CO 80549, USA

RECOMMENDATION: Additional Information → Telephone Hold: April 8, 2009

I. Purpose and Submission Summary

The purpose of this submission is to determine substantial equivalence with the following devices:

- K062143 Kozy Comfort™ Infant Positioner
- K060986 Head Bed™ Infant Positioner (foam cushion)
- K051300 Robin Hood Vest™ (Garment)
- K041996 Nightform™ Infant Sleep Positioner (mattress)

Reviewer's Note: The sponsor has provided enough information about the subject device and related predicate devices. --- Acceptable.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) - <i>Acceptable</i>	Y		
Truthful and Accuracy Statement - <i>Acceptable</i>	Y		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

	Yes	No	N/A
510(k) Summary or 510(k) Statement – <i>Summary provided - Acceptable</i>	Y		
Standards Form – <i>None declared.</i>	Y		

Reviewer's Note: The sponsor has provided all documents listed above and met the administrative requirements. - Acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile?		N	
Is the device reusable (not reprocessed single use)?			
Are "cleaning" instructions included for the end user? – Not Applicable	Y		

Description of the Devices:

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

Reviewer's Note: The sponsor has provided a clear description of the device. It is essentially a hat that the infant wears during sleep or awake. The hat will prevent the infant from rolling or turning from the repositioning aid. - Acceptable.

IV. Indications for Use

Subject Device:

Revised (02/25/2009):

The Life Innovations Infant Sleep Beanie is an over the counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants from 0-9 months of age.

Original:



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Predicate Device (K062143):

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly.

Predicate Device (K060986):

The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.

Predicate Device (K051300):

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

Predicate Device (K041996):

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.

(b)(4)



V. Predicate Device Comparison

The sponsor has provided the following table of comparison between the device and its predicate:

Device	Type
Infant Sleep Beanie	Garment
Kozy Comfort Infant	Positioner

63



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Positioner	
Head Bed Infant Positioner	Foam cushion
Robin Hood Vest	Garment
Nightform Infant Sleep Positioner	Mattress

Reviewer's Note: The sponsor provided predicate device information to establish that the subject devices are intended to be used for similar operations. --- Acceptable.

VI. Labeling

The sponsor has provided Size reference, Care Instructions, Directions for Use for the device

(b)(4)

Reviewer's Note: the labeling is incomplete because it did not include the Indication for Use statement. - Deficiency.

Reviewer's Note (04/06/2008): The sponsor has inserted the Indication for Use statement in S002 of the submission. - Acceptable.

VII. Sterilization/Shelf Life/Reuse

The product is not supplied sterile. The predicate device is also supplied non-sterile.

The submission did not mention Shelf Life, therefore shelf life is not claimed.

The device is apparently reusable. Cleaning instructions are provided in the labeling section of the submission. The predicate device has no cleaning instructions specified.

Reviewer's Note: - Adequate.

VIII. Biocompatibility

(b)(4)

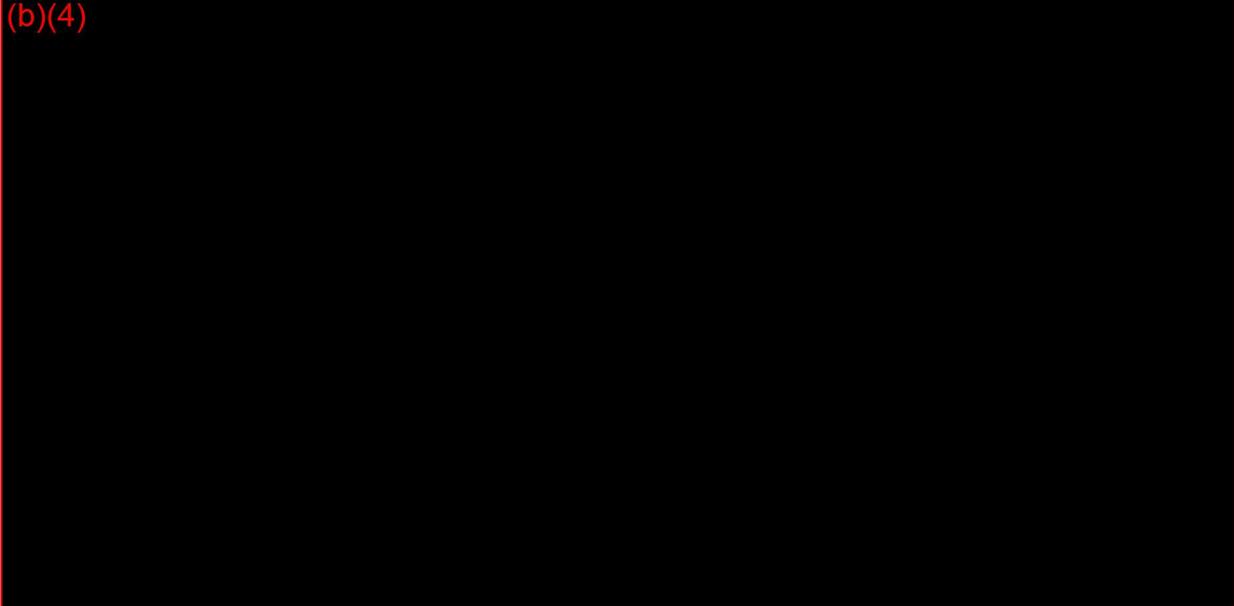


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



IX. Software

Not applicable. This device does not contain software - *Acceptable*.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

XII. Performance Testing – Animal

Not applicable. - *Acceptable*

XIII. Performance Testing – Human Factors

Not applicable - *Acceptable*.

XIV. Substantial Equivalence Discussion (TELEPHONE HOLD – April 6, 2009)

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:

66



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

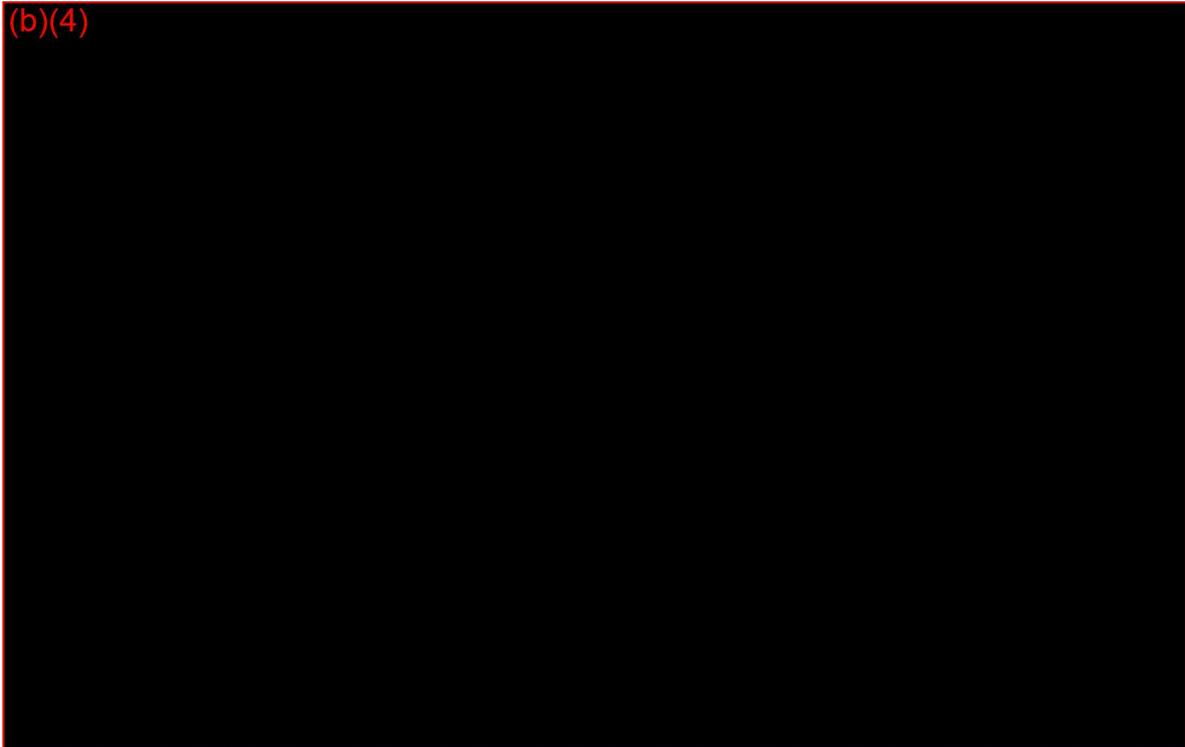
Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
The sponsor needs to provide supporting evidence that the weight of the hat does not pose risk to the infants.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
The sponsor needs to complete the labeling section of the submission to add indications for use.
(b)(4)
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

We found the following deficiencies with the submission:

(b)(4)



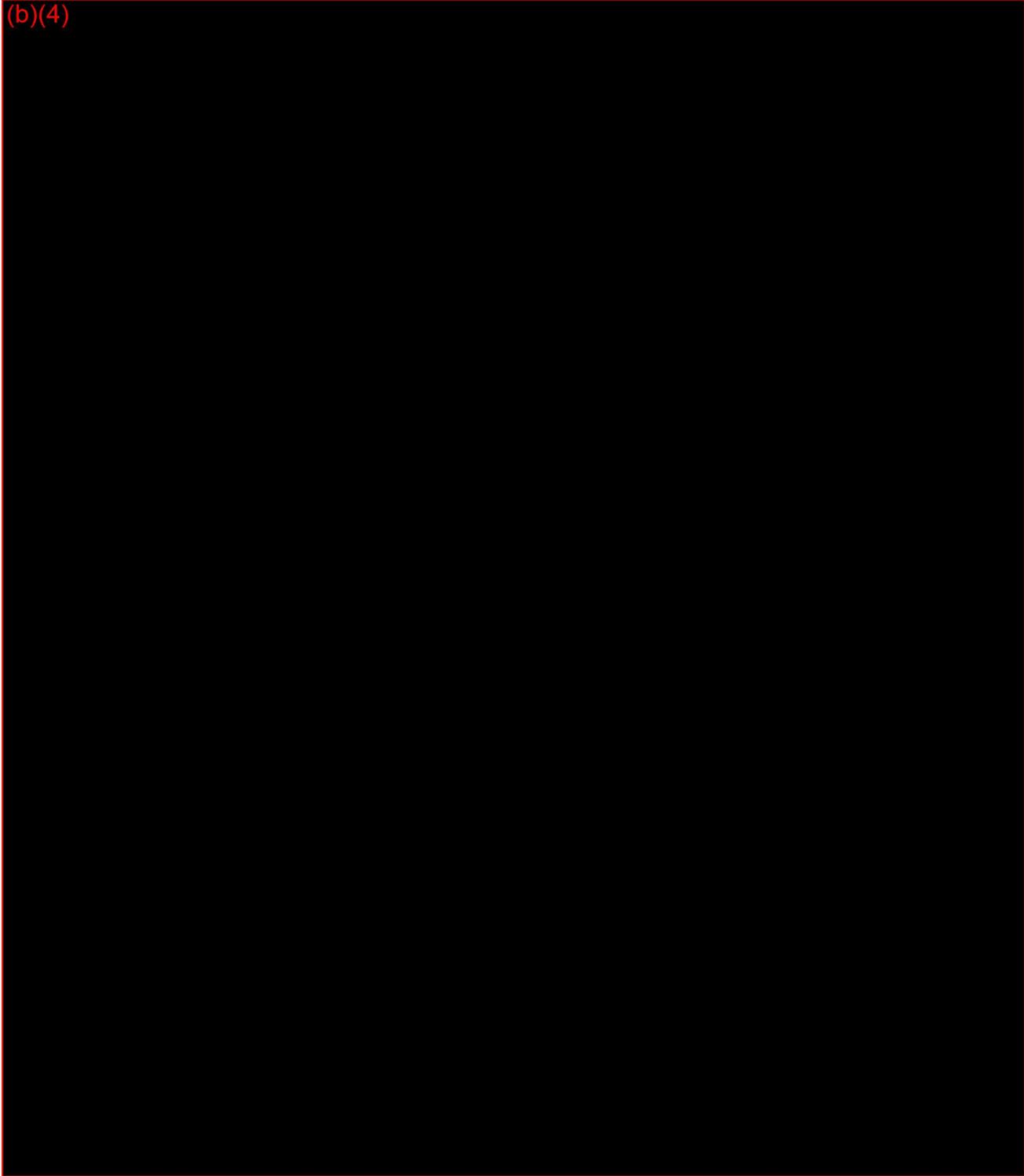


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

Reviewer's Note (03/09/2009): The sponsor has responded by revising the labeling to include size suggestions. Dr. Joy Samuels-Reid reviewed this information and found them to be adequate. – Acceptable.

(b)(4)

Additional Deficiencies (S001)

1. The labeling you have provided in your submission is incomplete. You have not included the Indications for Use as a part of your labeling. Please clearly identify and insert the Indications for Use statement as part of your product Labeling. Please provide an update version of your product labeling.

Reviewer's Note (04/06/2009): The sponsor has responded by inserting the Indications for Use statement. – Acceptable.

(b)(4)

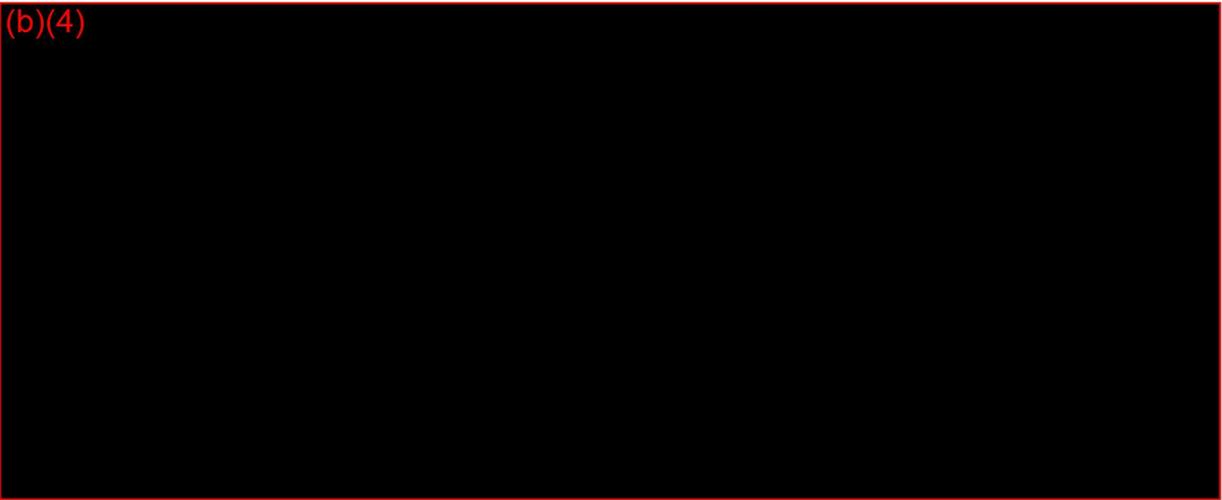


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

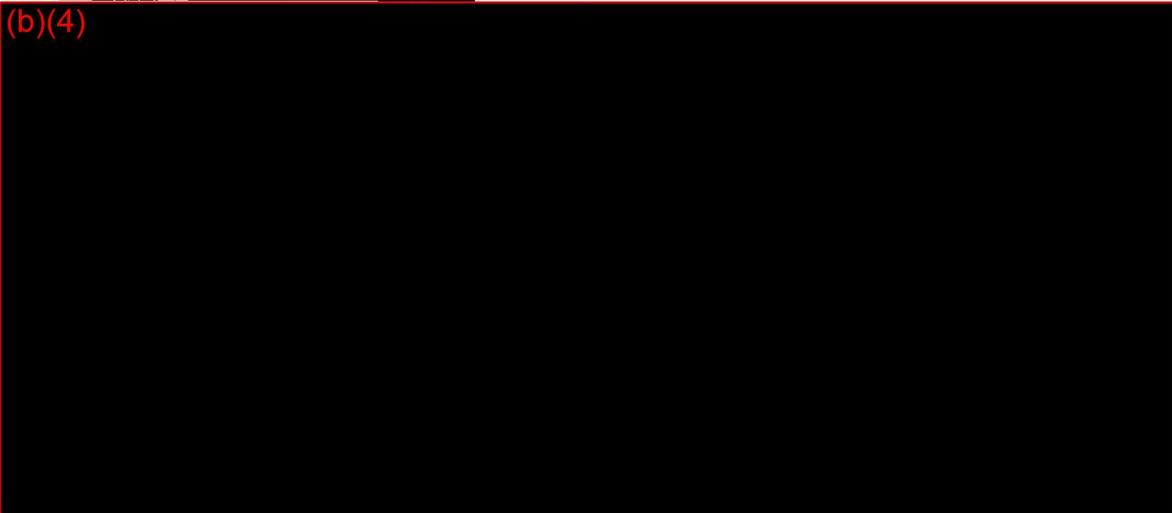
Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)



Additional Deficiencies (S002)

(b)(4)



XVI. Contact History

1. 03/03/2009. Called the sponsor request for updated IFU statement with "Over-the-Counter use" checked. Additionally, need the sponsor to update the 510(k) Summary to make the "Intended Use" section identical to the IFU statement.
2. 03/04/2009. Sponsor email me with the revised IFU statement and the 510(k) Summary.

XVII. Recommendation

Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric position holder
Regulatory Class: Class I



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Product Code: FRP

RECOMMENDATION: Telephone Hold: April 9, 2009

[Handwritten signature]

Reviewer

[Handwritten signature]

Branch Chief

[Handwritten date]

Date
[Handwritten date]

Date



COVER SHEET MEMORANDUM

From: Reviewer Name _____
Subject: 510(k) Number K082367(S)
To: The Record

- Please list CTS decision code _____
- 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 _____ (k) n. _____ <i>Attach IFU</i>		
Truthful and Accurate Statement. Is the device Class III? If yes, does firm include Class III Summary? <i>Must be present for a Final Decision</i>		
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)		
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)		
Is this device intended for pediatric use only?		
Is this a prescription device? (If both prescription & OTC, check both boxes.)		
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>		
_____ include animal tissue source?		
All Pediatric Patients age <= 21		
Neonate/Newborn (Birth to 28 days)		
Infant (29 days - < 2 years old)		
Child (2 years - < 12 years old)		
Adolescent (12 years - < 18 years old)		
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.)		
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)		
_____ anotechnology		

Shen, Lening

From: Shen, Lening
Sent: Monday, March 16, 2009 7:01 PM
To: 'jsco704@aol.com'
Cc: Colburn, Scott A; Zimlik, Charles L* (CDRH)
Subject: 510(k) submission K082367/S001: Infant Sleep Beanie

Jane Scott, CEO
Life Innovations, LLC
P.O. Box 148
Wellington, CO 80549
jsco704@aol.com

Dear Ms. Scott,

We have reviewed your response to our November 6, 2008 email request for additional information regarding your 510(k) submission K082367: Infant Sleep Beanie. To complete the review of your submission, we request the following additional information:

1. The labeling you have provided in your submission is incomplete. You have not included the Indications for Use as a part of your labeling. Please clearly identify and insert the Indications for Use statement as part of your product Labeling. Please provide an update version of your product labeling.

(b)(4)



Please confirm that you have received this e-mail. I am placing this submission on hold. All information you submit in response to this request should be send to our document control center as a supplement to this 510(k) (K082367) submission. If you have any questions, please contact me.

Sincerely,

Lening Shen
General Engineer
General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: (240) 276-3713
Fax: (240) 276-3789



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K082367 S001

Date: March 16, 2009

To: The Record

Office: HFZ-480

From: Lening Shen, General Engineer

Division: DAGID/GHDB

510(k) Holder: Life Innovations, LLC

Device Name: Infant Sleep Beanie

Classification: Class I 880.5680, FRP, Pediatric position holder

Contact: Jane Scott, CEO

Phone: 208-316-5297

Fax: 208-734-9941

Email: jsco704@aol.com

Address: P.O. Box 148, Wellington, CO 80549, USA

RECOMMENDATION: Additional Information → Telephone Hold: March 16, 2009

I. Purpose and Submission Summary

The purpose of this submission is to determine substantial equivalence with the following devices:

- K062143 Kozy Comfort™ Infant Positioner
- K060986 Head Bed™ Infant Positioner (foam cushion)
- K051300 Robin Hood Vest™ (Garment)
- K041996 Nightform™ Infant Sleep Positioner (mattress)

Reviewer's Note: The sponsor has provided enough information about the subject device and related predicate devices. — Acceptable.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) - <i>Acceptable</i>	Y		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

	Yes	No	N/A
Truthful and Accuracy Statement - <i>Acceptable</i>	Y		
510(k) Summary or 510(k) Statement - <i>Summary provided - Acceptable</i>	Y		
Standards Form - <i>None declared.</i>	Y		

Reviewer's Note: The sponsor has provided all documents listed above and met the administrative requirements. - Acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile?		N	
Is the device reusable (not reprocessed single use)? - <i>Device is a hat.</i>		N	
Are "cleaning" instructions included for the end user? - Not Applicable			

Description of the Devices:

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

Reviewer's Note: The sponsor has provided a clear description of the device. It is essentially a hat that the infant wears during sleep or awake. The hat will prevent the infant from rolling or turning from the repositioning aid. - Acceptable.

IV. Indications for Use

Subject Device:

Revised (02/25/2009):

The Life Innovations Infant Sleep Beanie is an over the counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants from 0-9 months of age.

Original:



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Predicate Device (K062143):

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly.

Predicate Device (K060986):

The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.

Predicate Device (K051300):

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

Predicate Device (K041996):

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.

(b)(4)

V. Predicate Device Comparison

The sponsor has provided the following table of comparison between the device and its predicate:

Device	Type
Infant Sleep Beanie	Garment
Kozy Comfort Infant	Positioner



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Positioner	
Head Bed Infant Positioner	Foam cushion
Robin Hood Vest	Garment
Nightform Infant Sleep Positioner	Mattress

Reviewer's Note: The sponsor provided predicate device information to establish that the subject devices are intended to be used for similar operations. -- Acceptable.

VI. Labeling

The sponsor has provided Size reference, Care Instructions, Directions for Use for the device.

(b)(4)

VII. Sterilization/Shelf Life/Reuse

The product is not supplied sterile. Therefore, this section does not apply.

The submission did not mention Shelf Life.

The device is apparently reusable being it is a hat.

Reviewer's Note: - Adequate.

VIII. Biocompatibility

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

IX. Software

Not applicable. This device does not contain software - *Acceptable*.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4)

XII. Performance Testing – Animal

Not applicable. - *Acceptable*

XIII. Performance Testing – Human Factors

Not applicable - *Acceptable*.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

XIV. Substantial Equivalence Discussion (TELEPHONE HOLD – March 16, 2009)

	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		X	If NO = Request Data
9. Data Demonstrate Equivalence?		X	Final Decision: TH

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
The sponsor needs to provide supporting evidence that the weight of the hat does not pose risk to the infants.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:

(b)(4)



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

The sponsor needs to complete the labeling section of the submission to add indications for use.

(b)(4)

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

XV. Deficiencies

We found the following deficiencies with the submission:

(b)(4)



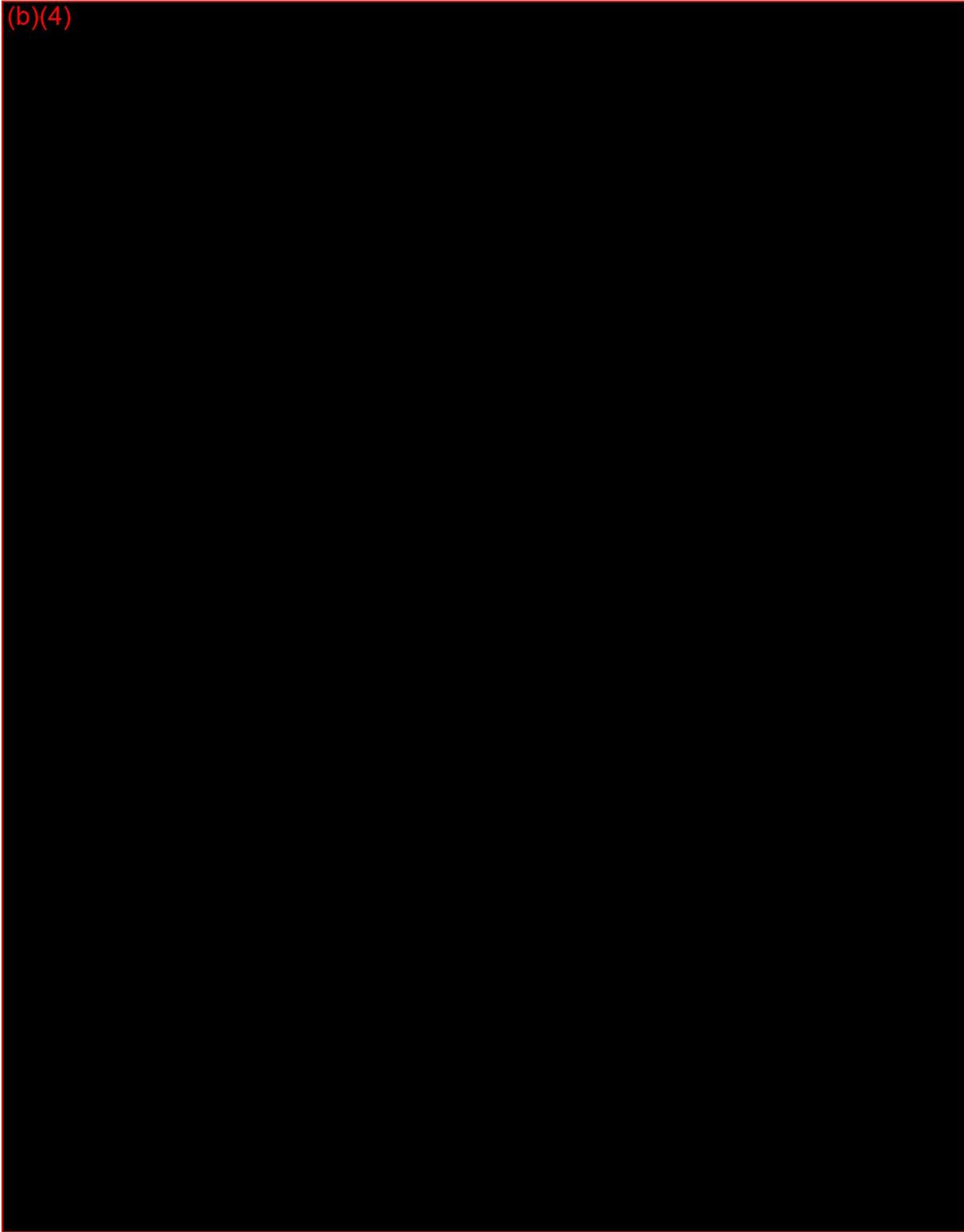


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

A large black rectangular redaction box covers the majority of the page content, starting below the header and ending above the footer. The text "(b)(4)" is written in red at the top left corner of this redacted area.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

Reviewer's Note (03/09/2009): The sponsor has responded by revising the labeling to include size suggestions. Dr. Joy Samuels-Reid reviewed this information and found them to be adequate. – Acceptable.

(b)(4)

A large black rectangular redaction box covering the majority of the page's content.

Additional Deficiencies (S001)

1. The labeling you have provided in your submission is incomplete. You have not included the Indications for Use as a part of your labeling. Please clearly identify and insert the Indications for Use statement as part of your product Labeling. Please provide an update version of your product labeling.

(b)(4)

A large black rectangular redaction box covering the majority of the page's content.

XVI. Contact History

1. 03/03/2009. Called the sponsor request for updated IFU statement with "Over-the-Counter use" checked. Additionally, need the sponsor to update the 510(k) Summary to make the "Intended Use" section identical to the IFU statement.
2. 03/04/2009. Sponsor email me with the revised IFU statement and the 510(k) Summary.

XVII. Recommendation

Regulation Number: 21 CFR 880.5680
Regulation Name: Pediatric position holder
Regulatory Class: Class I



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Product Code: FRP

RECOMMENDATION: Telephone Hold: March 16, 2009

[Handwritten Signature]

Reviewer

[Handwritten Signature]

Branch Chief

CZ 3/16/09

3/16/09

Date

3/16/09

Date

Shen, Lening

From: Samuels-Reid, Joy H.
Sent: Monday, March 02, 2009 2:38 PM
To: Shen, Lening
Subject: Response to questions

Re: Infant Sleep Beanie
The responses provided are reasonable.

Joy Samuels-Reid, M.D., FAAP
Chief Medical Officer,
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Center for Devices and Radiological Health
Office of Device Evaluation
9200 Corporate Blvd.
Tel: 240-276-3707
FX: 240-276-3789
Joy.Samuels-Reid@fda.hhs.gov

Shen, Lening

From: jsco704@aol.com
Sent: Wednesday, March 04, 2009 10:45 AM
To: Shen, Lening
Subject: Re: Requested revision 510(K) K082367
Attachments: REVISED_03_03_510(k)_Summary_INFANT_SLEEP_BEANIE.doc;
REVISED_03_03_Feb_2009_Indications_for_Use_INFANT_SLEEP_BEANIE.doc

Thank you for your telephone call. I have made requested changes and have included them as attachments with this email.

Respectfully,
Jane Scott

A Good Credit Score is 700 or Above. See yours in just 2 easy steps!

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Prescription Use _____
(Part 21 CFR §801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Life Innovations, LLC
Revised February, 2009

Life Innovations
Limited Liability Company

510(k) SUMMARY

Submitter: Life Innovations, LLC.
Address: P.O. Box 148
Wellington, CO 80549
Phone Number: (208) 420-5059
Fax Number: (208) 734-9941
Contact Person: Jane Y. Scott, M.D.
Chief Executive Officer
Jsc0704@aol.com

Date Prepared: March 3, 2009

Device Trade or Proprietary Name: Infant Sleep Beanie
Device Common or Usual Name: Pediatric position holder

Classification: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Panel: General Hospital and Personal Use Devices
Classification: Class I (reserved); GMP Exempt
Classification Code: FRP

Predicate Device(s):

Kozy Comfort™ Infant Positioner	K062143
Head Bed™ Infant Positioner	K060986
Robin Hood Vest™	K051300
Nightform™ Infant Sleep Positioner	K041996

Device Description: The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.

Intended Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Technological Characteristics: The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled. The Life Innovations Infant Sleep Beanie comes in multiple colors and designs to coordinate with infant clothing.

Performance Summary: The FDA has not established special controls or standards for this device.



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name LENING SHEN
Subject: 510(k) Number K082367
To: The Record

- Please list CTS decision code TA
- Refused to accept (Note: this is considered the first review cycle. See Screening Checklist http://eroom.fda.gov/RoomReq/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	<input checked="" type="checkbox"/>	<input type="checkbox"/>
510(k) Summary 510(k) Statement	Attach Summary	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Truthful and Accurate Statement.	Must be present for a Final Decision	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is the device Class III?		<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, does firm include Class III Summary?	Must be present for a Final Decision	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf).		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/RoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20REVISED%203-12-03).DOC)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff - MDJ/RMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this device intended for pediatric use only?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is this a prescription device? (If both prescription & OTC, check both boxes.)	<u>deficient</u>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is clinical data necessary to support the review of this 510(k)?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Did the application include a completed FORM FDA-3674, Certification with Requirements of Clinical Trials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this device include an Animal Tissue Source?		<input type="checkbox"/>	<input checked="" type="checkbox"/>
All Pediatric Patients age <= 21		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Neonate/Newborn (Birth to 28 days)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Infant (29 days - < 2 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Child (2 years - < 12 years old)		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Adolescent (12 years - < 18 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)		<input type="checkbox"/>	<input checked="" type="checkbox"/>
Nanotechnology		<input type="checkbox"/>	<input checked="" type="checkbox"/>

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	Class*	Product Code	

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

Review: _____
 (Branch Chief) *CE 11/6/08* *GM03* (Branch Code) *11/6/08* (Date)

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

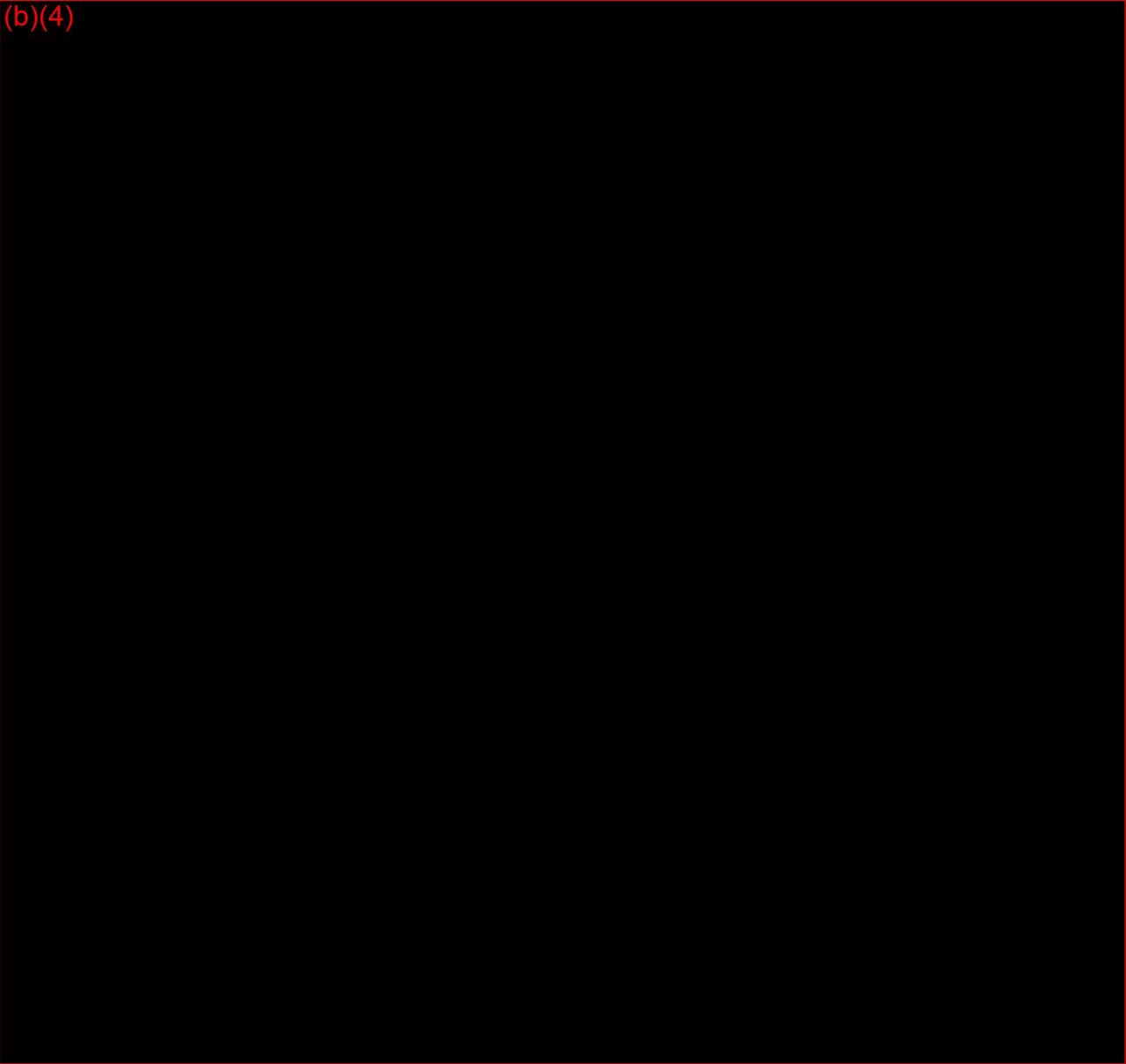
From: Shen, Lening
Sent: Thursday, November 06, 2008 10:44 AM
To: 'jsco704@aol.com'
Cc: Watson, Anthony; Zimlik, Charles L* (CDRH)
Subject: 510(k) submission K082367: Infant Sleep Beanie

Jane Scott, CEO
Life Innovations, LLC
P.O. Box 148
Wellington, CO 80549
jsco704@aol.com

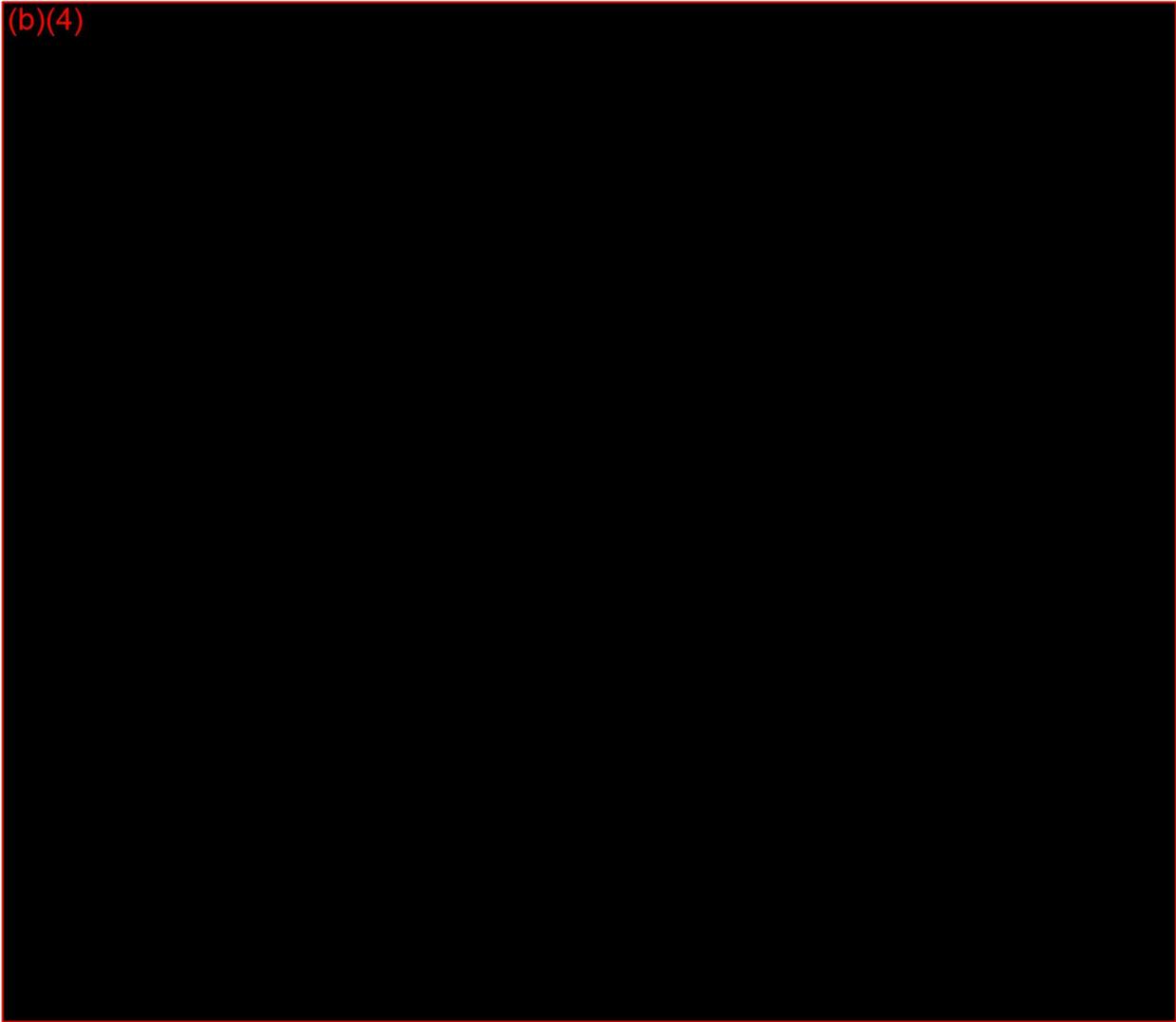
Dear Ms. Scott,

We have reviewed your 510(k) submission K082367: Infant Sleep Beanie. To complete the review of your submission, we request the following additional information:

(b)(4)



(b)(4)



3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

(b)(4)



Please confirm that you have received this e-mail. I am placing this submission on hold. All information you submit in response to this request should be send to our document control center as a supplement to this 510(k) (K082367) submission. If you have any questions, please contact me.

Lening Shen
General Engineer

General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: (240) 276-3713
Fax: (240) 276-3789



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional/Abbreviated**

K082367

Date: November 4, 2008

To: The Record

Office: HFZ-480

From: Lening Shen, General Engineer

Division: DAGID/GHDB

510(k) Holder: Life Innovations, LLC

Device Name: Infant Sleep Beanie

Classification: Class I 880.5680, FRP, Pediatric position holder

Contact: Jane Scott, CEO

Phone: 208-420-5059

Fax: 208-734-9941

Email: jsco704@aol.com

Address: P.O. Box 148, Wellington, CO 80549, USA

RECOMMENDATION: Additional Information → Telephone Hold: November 4, 2008

I. Purpose and Submission Summary

The purpose of this submission is to determine substantial equivalence with the following devices:

- K062143 Kozy Comfort™ Infant Positioner
- K060986 Head Bed™ Infant Positioner (foam cushion)
- K051300 Robin Hood Vest™ (Garment)
- K041996 Nightform™ Infant Sleep Positioner (mattress)

Reviewer's Note: The sponsor has provided enough information about the subject device and related predicate devices. --- Acceptable.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC) - <i>Acceptable</i>	Y		



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

	Yes	No	N/A
Truthful and Accuracy Statement - <i>Acceptable</i>	Y		
510(k) Summary or 510(k) Statement - <i>Summary provided - Acceptable</i>	Y		
Standards Form - <i>None declared.</i>	Y		

Reviewer's Note: The sponsor has provided all documents listed above and met the administrative requirements. - Acceptable.

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		N	
Is the device an implant (implanted longer than 30 days)?		N	
Does the device design use software?		N	
Is the device sterile? - <i>there are 2 versions: Sterile and non-sterile</i>		N	
Is the device reusable (not reprocessed single use)? - <i>Device is a hat.</i>		N	
Are "cleaning" instructions included for the end user? - Not Applicable			

Description of the Devices:

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

Reviewer's Note: The sponsor has provided a clear description of the device. It is essentially a hat that the infant wears during sleep or awake. The hat will prevent the infant from rolling or turning from the repositioning aid. - Acceptable.

IV. Indications for Use

Subject Device:

The Life Innovations Infant Sleep Beanie is a first line repositioning device to aid in the prevention and/or treatment of mild to moderate deformational positional plagiocephaly. The Infant Sleep Beanie is intended for healthy infants from 0-9 months.

Predicate Device (K062143):

The Kozy Comfort product is indicated for healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition know as deformational (or positional) plagiocephaly



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Predicate Device (K060986):

The Head Bed™ infant positioner is indicated for infants aged 0-6 months to aid in the prevention of deformational plagiocephaly..

Predicate Device (K051300):

The Robin Hood Vest™ is intended for use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.

Predicate Device (K041996):

The NightForm product is indicated for healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.



V. Predicate Device Comparison

The sponsor has provided the following table of comparison between the device and its predicate:

Device	Type
Infant Sleep Beanie	Garment
Kozy Comfort Infant Positioner	Positioner
Head Bed Infant Positioner	Foam cushion
Robin Hood Vest	Garment
Nightform Infant Sleep Positioner	Mattress

Reviewer's Note: The sponsor provided predicate device information to establish that the subject devices are intended to be used for similar operations. --- Acceptable.

VI. Labeling

The sponsor has provided Size reference, Care Instructions, Directions for Use for the device.





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Reviewer's Note: - Acceptable.

VII. Sterilization/Shelf Life/Reuse

The product is not supplied sterile. Therefore, this section does not apply.

Reviewer's Note: - Adequate.

VIII. Biocompatibility

(b)(4)

A large black rectangular redaction box covering the entire content of section VIII.

IX. Software

Not applicable. This device does not contain software - *Acceptable.*

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable.

XI. Performance Testing – Bench

(b)(4)

A large black rectangular redaction box covering the entire content of section XI.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)

XII. Performance Testing – Animal

Not applicable. - *Acceptable*

XIII. Performance Testing – Human Factors

Not applicable - *Acceptable*.

XIV. Substantial Equivalence Discussion (REQUIRES ADDITIONAL INFORMATION – October 31, 2008)

	Yes	No	
1. Same Indication Statement?		X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?			If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?			If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?			If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See

http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: The new indication is substantially different from that of the predicates'.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

XV. Deficiencies

We found the following deficiencies with the submission:

(b)(4)

A large black rectangular redaction box covers the majority of the page content, starting below the "Deficiencies" section and extending nearly to the bottom of the page. The text "(b)(4)" is written in red at the top left corner of this redacted area.

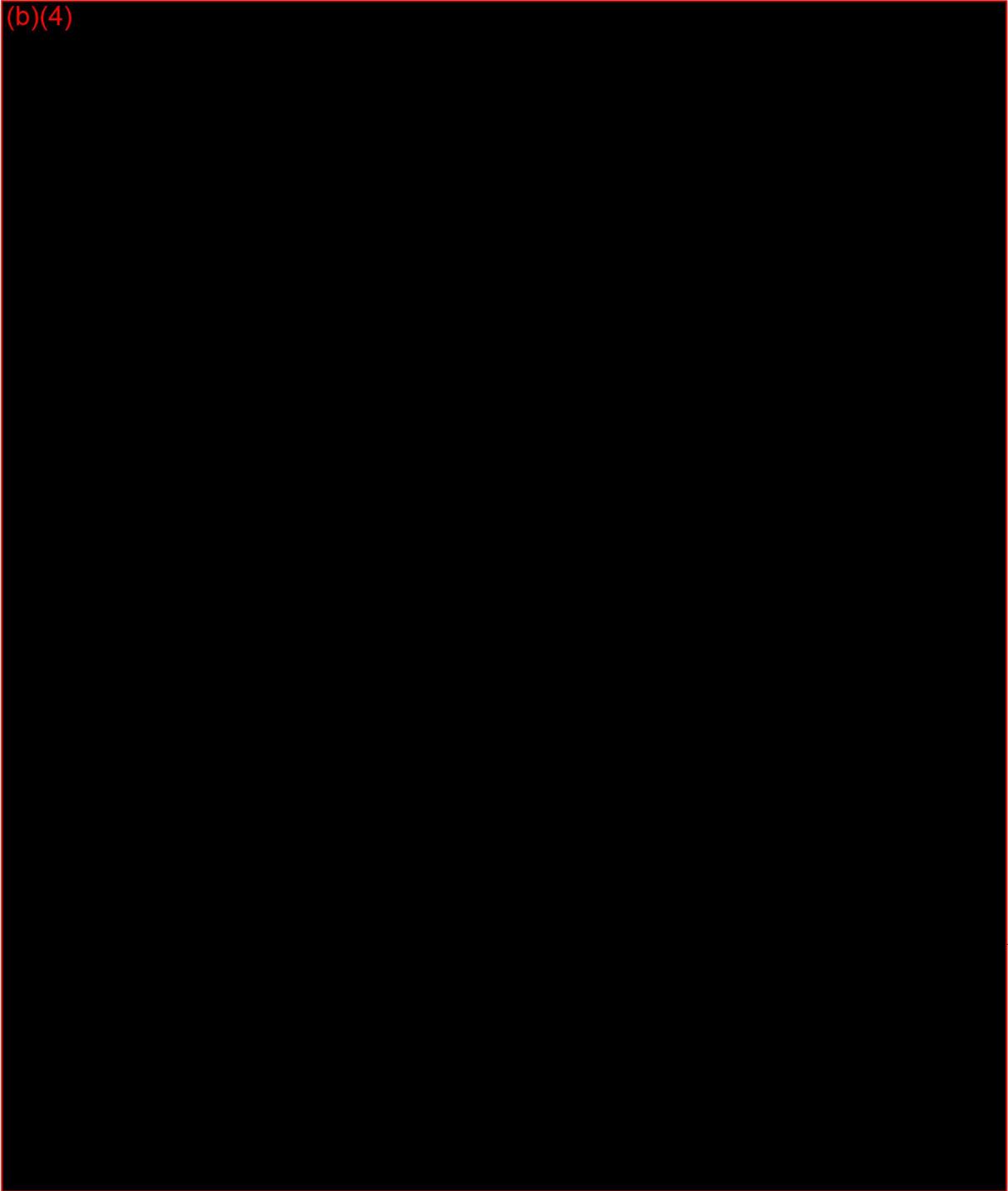


DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

(b)(4)





DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

- 3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

(b)(4)



XVI. Contact History

XVII. Recommendation

Regulation Number: 21 CFR 880.5680
 Regulation Name: Pediatric position holder
 Regulatory Class: Class I
 Product Code: FRP

RECOMMENDATION: Additional Information → Telephone Hold: November 4, 2008



 Reviewer

11/4/08

 Date



 Branch Chief

11/6/08

 Date

07 11/6/08

Shen, Lening

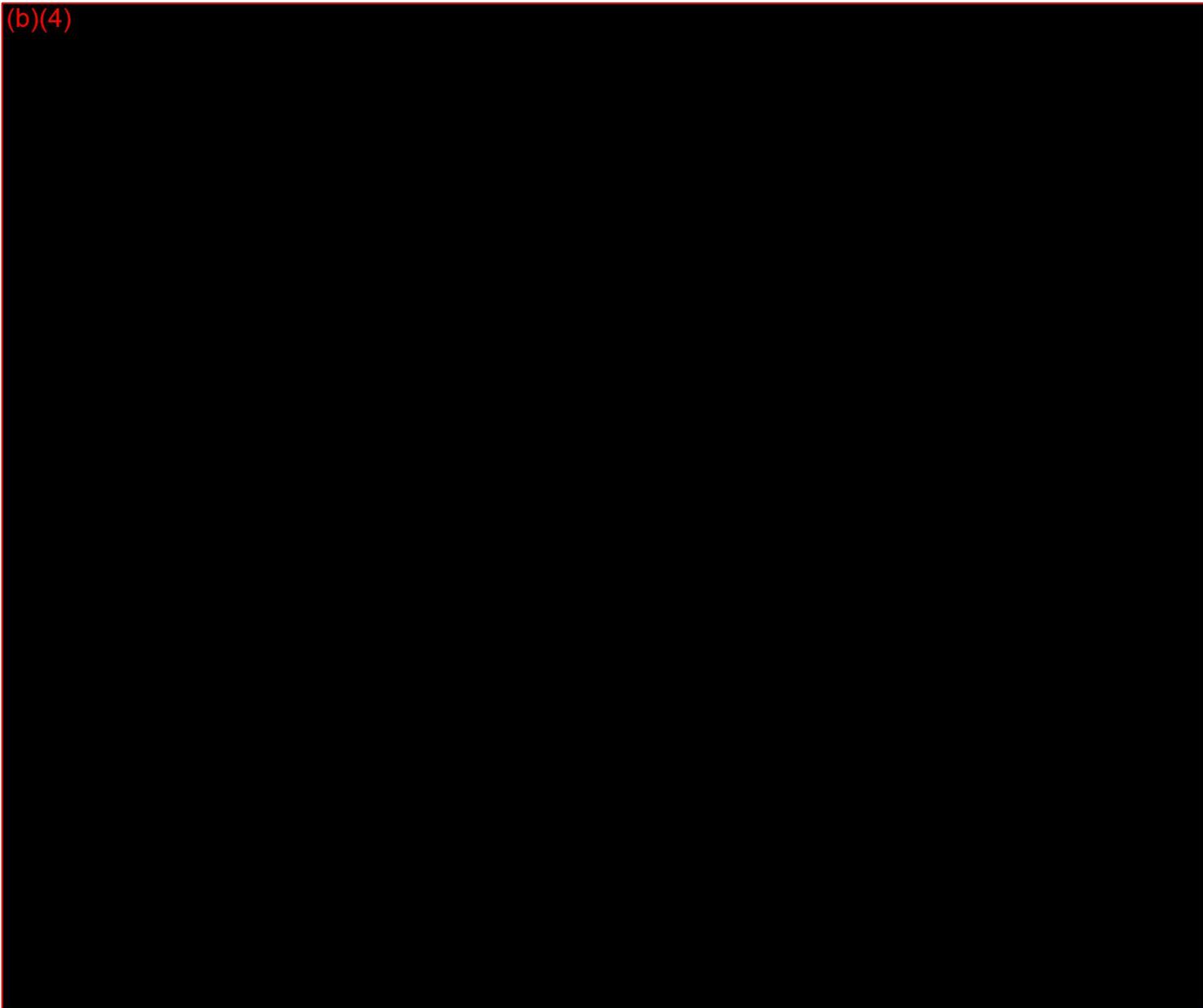
From: Shen, Lening
Sent: Thursday, November 06, 2008 10:44 AM
To: 'jsco704@aol.com'
Cc: Watson, Anthony; Zimlik, Charles L* (CDRH)
Subject: 510(k) submission K082367: Infant Sleep Beanie

Jane Scott, CEO
Life Innovations, LLC
P.O. Box 148
Wellington, CO 80549
jsco704@aol.com

Dear Ms. Scott,

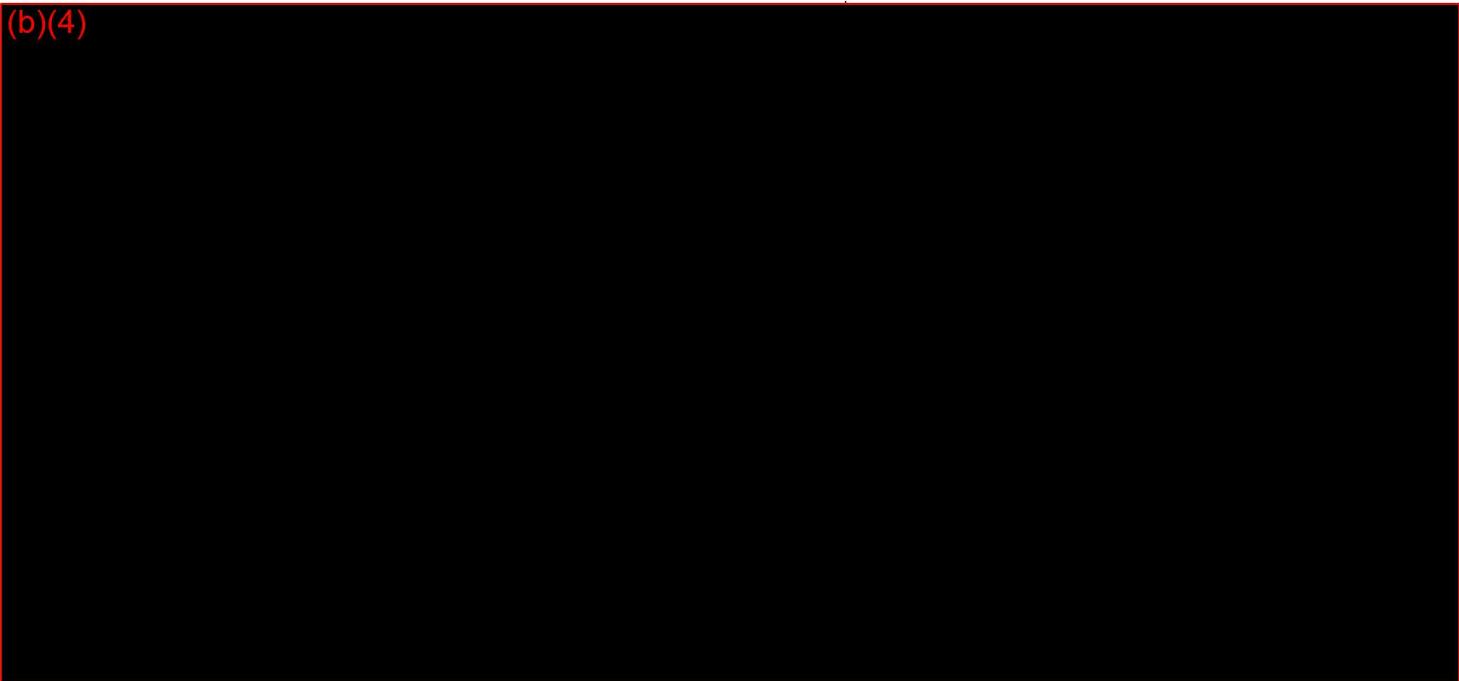
We have reviewed your 510(k) submission K082367: Infant Sleep Beanie. To complete the review of your submission, we request the following additional information:

(b)(4)



150

(b)(4)



3. Please indicate all the sizes and ranges of your device for which you are seeking clearance to market your product. In addition, you should provide a tool to help parents/guardians, or clinicians to determine the appropriate selection from the different sized hats to ensure proper fit.

(b)(4)



Please confirm that you have received this e-mail. I am placing this submission on hold. All information you submit in response to this request should be send to our document control center as a supplement to this 510(k) (K082367) submission. If you have any questions, please contact me.

Lening Shen
General Engineer
General Hospital Devices Branch
Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: (240) 276-3713
Fax: (240) 276-3789

From: Joy Samuels-Reid, M. D., FAAP.
Chief Medical Officer
Acting Deputy Division Director, DAGID/CDRH

To: Mr. Lening Shen
General Engineer, GHDB/DAGID

Document: K082367

Sponsor: Life Innovations, Llc

Device: Infant Sleep Beanie

Date: October 23, 2008

Device Description

The Infant Sleep Beanie is a form-fitting hat that is intended to aid in the prevention and/treatment of mild to moderate plagiocephaly. The hat aids in the repositioning of the head to different positions on an as-needed basis. The hat restricts rolling or turning away from the repositioning aid. The Infant Sleep Beanie is intended for healthy babies from 0-9 months. The device is available in several sizes to accommodate the baby's growing head size. It is made of a cotton blend material and is washable. The sponsor states that it is comfortable to wear.

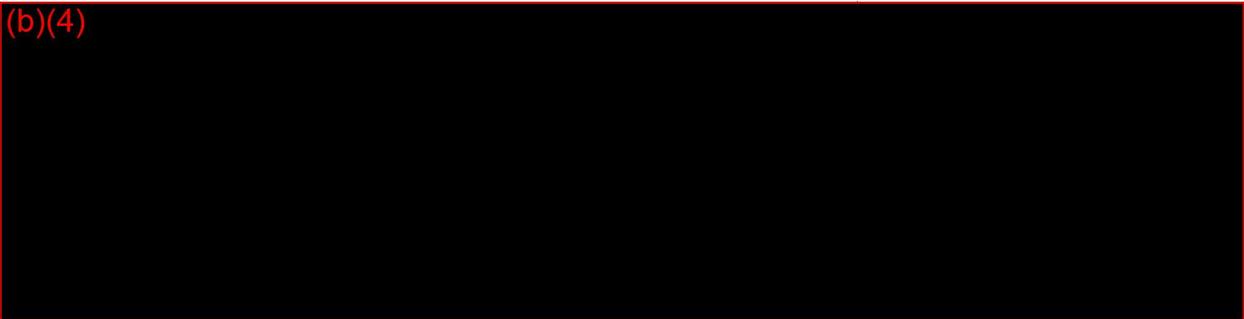
Background

Positional/deformational plagiocephaly is defined as asymmetry of the skull due to many factors, including birthing-related issues, congenital deformities and positional deformation, which may result in flattening of the head. Prolonged periods in the same position, especially lying on the back, are a causative factor. The incidence of positional plagiocephaly has increased following recommendations by the American Academy of Pediatrics (AAP) to place babies on their backs during sleep ("Back to Sleep" Campaign) in an effort to reduce Sudden Infant Death Syndrome (SIDS). Repositioning has been recommended by clinicians as a way to prevent positional plagiocephaly. It is thought to be effective if initiated before six months of age.

Reviewer's Comments

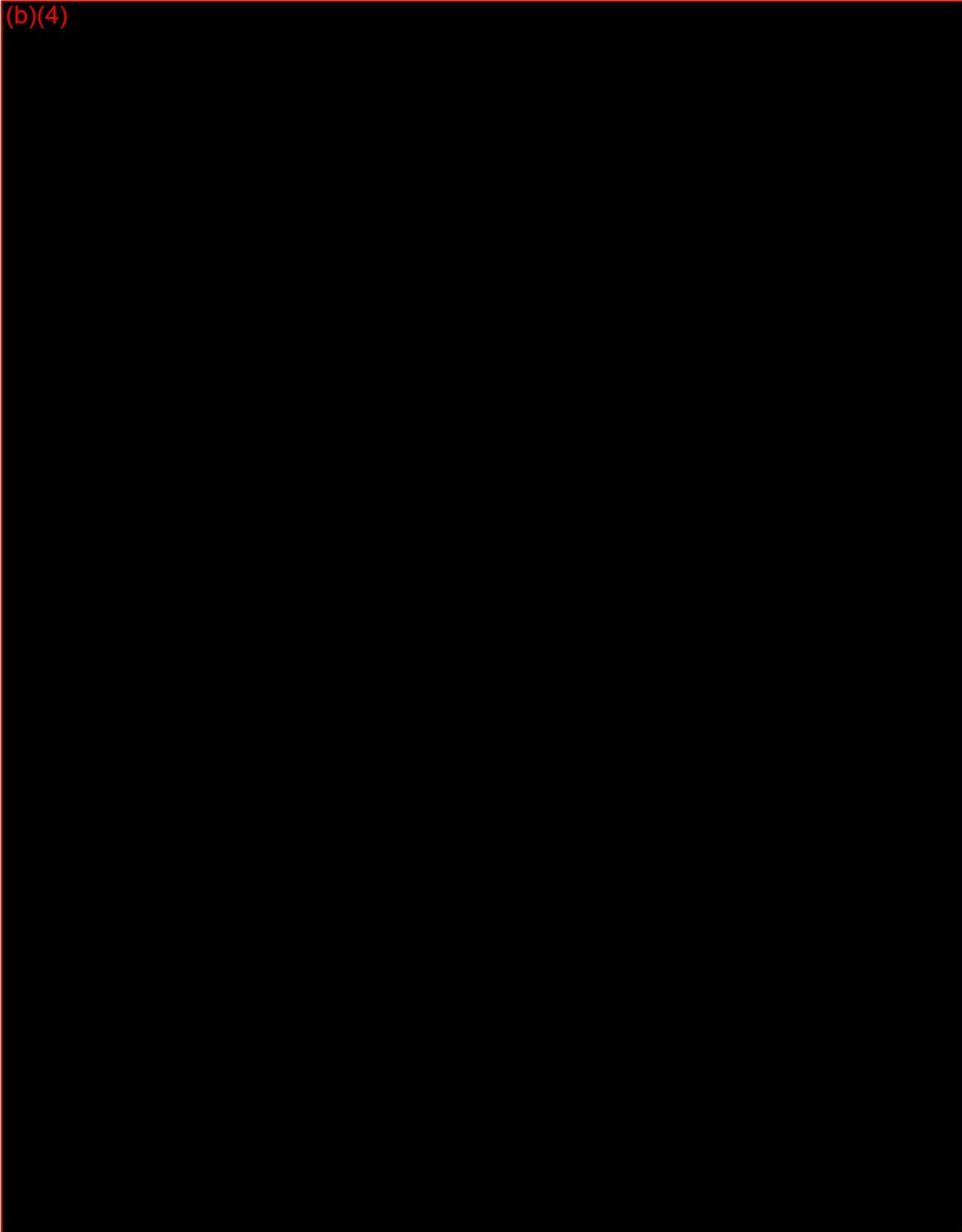
The subject device is intended as a "first line repositioning aid," according to the sponsor. It may be used during sleep or while awake. Other repositioning devices exist to aid in prevention of positional plagiocephaly. Cranial orthotic devices that treat the condition are available in the form of custom-made helmets that are used for cranial reshaping for more advanced cases.

(b)(4)



152

(b)(4)



Joy Samuels-Reid, M.D.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

February 26, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

K082367/8

*Life Innovations
Limited Liability Company*

February 25, 2009

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

SUBJECT: 510(k) Premarket Notification K082367
Response to Reviewer's Questions
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application is on hold for 30 days pending receipt of the additional information "AI" that was requested by the Office of Device Evaluation. We requested, and was granted, extensions to the "hold" time in order to prepare our response.

The following additional information is provided in response to the Reviewer's questions.

Question 1:

(b)(4)

(b)(4) The Reviewer also asked if the Infant Sleep Beanie is for prescription use or over-the-counter use.

Response: The Life Innovations Infant Sleep Beanie is a cap, or hat, intended to help parents reposition a back-sleeping infant's head to prevent the condition known as deformational (or positional) plagiocephaly. It is a consumer product ("over-the-counter use") for healthy, non-ambulating infants 0-9 months of age. (b)(4)

(b)(4) To be clear that the Infant Sleep Beanie has the same intended use as the other cleared devices in the §880.5680 classification, we are providing revised substantial

equivalence information comparing predicate devices in the pediatric position holder classification.* A revised Indications for Use statement is also attached.

DEVICE	510(k) #	INTENDED USE	Type
Infant Sleep Beanie	K082367	<i>For healthy, non-ambulating infants 0-9 months to aid in the prevention of deformational positional plagiocephaly. Deformational (or positional) plagiocephaly may arise from consistent back-sleeping postures.</i>	garment
Kozy Comfort™ Infant Positioner	K062143	<i>For healthy infants 0-12 months to aid in the prevention of skull deformities that may arise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.</i>	Bedding/pillow
Head Bed™ Infant Positioner	K060986	<i>For infants aged 0-6 months to aid in the prevention of deformational plagiocephaly.</i>	Bedding/foam cushion placed around the head
Robin Hood Vest™	K051300	<i>For use in healthy infants aged 0-15 months to aid in the prevention of skull deformities that can arise from consistent back-sleeping postures, the condition known as deformational (or positional) plagiocephaly.</i>	garment
Nightform™ Infant Sleep Positioner	K041996	<i>For healthy infants 0-9 months to aid in the prevention of skull deformities that can rise from consistent back-sleeping postures, namely the condition known as deformational (or positional) plagiocephaly.</i>	Bedding/mattress

Question 2:

(b)(4)

Question 3:

(b)(4)

Question 4:

(b)(4)

* 21CFR §880.5680 -- Pediatric position holder (FRP), Class I (reserved); Exempt from GMP (21CFR Part 820). The pediatric position holder is not automated with computer software per §820.30 (a) (2) (i) and is not listed in §820.30 (a) (2) (ii) as a Class I device subject to design controls.

(b)(4)

(b)(4)

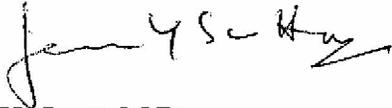
To reflect the revision to the indication for use, we are also providing a revised Summary of Safety and Effectiveness.

I would appreciate hearing from you regarding this request for an extension of time at your earliest convenience.

Very truly yours,

Life Innovations, LLC

Signed:



Jane Y. Scott, M.D.
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jsc0704@aol.com

Attachments:

Indications for Use Statement
Risk Analysis Report
Labeling (revised February, 2009)
Summary of Safety and Effectiveness (revised)

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Prescription Use _____
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Life Innovations, LLC
Revised February, 2009

Life Innovations, LLC

Infant Sleep Beanie

**RISK ANALYSIS
REPORT**

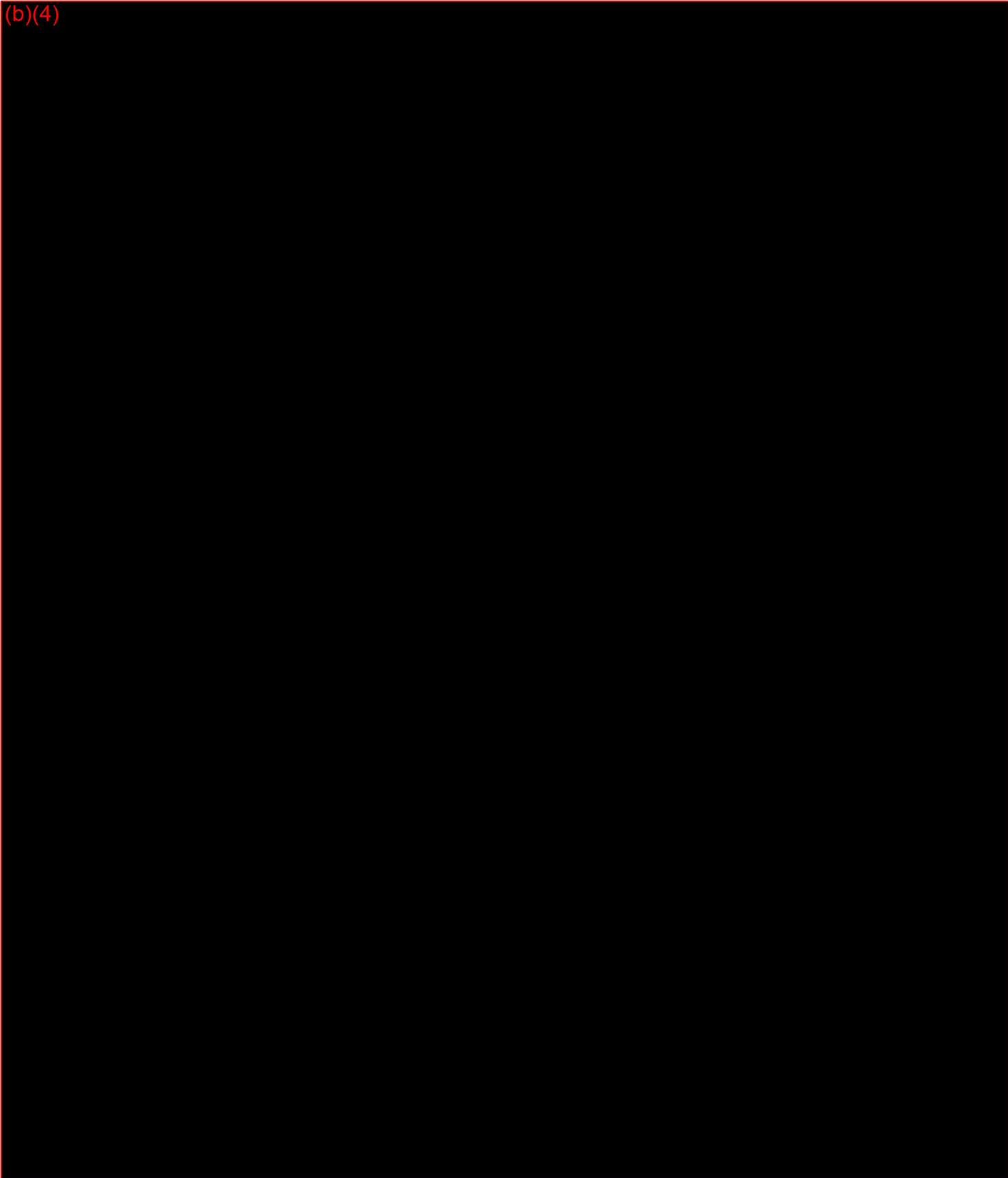
CONFIDENTIAL

CONFIDENTIAL

Risk Analysis – Life Innovations Infant Sleep Beanie

Date: 01/04/2009

(b)(4)



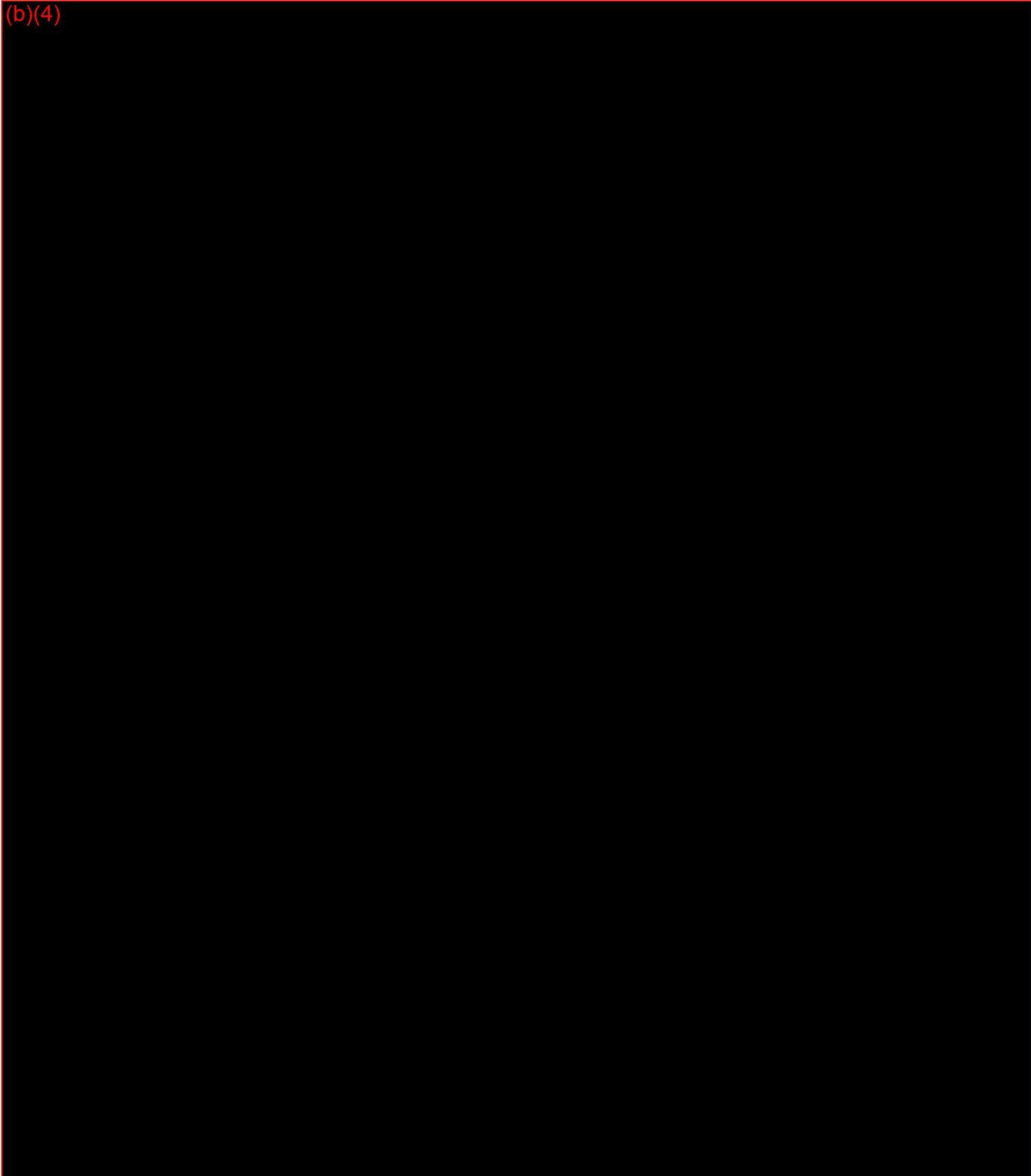
CONFIDENTIAL

General Risk Analysis for: Infant Sleep Beanie

Life Innovations LLC

Date: 01/04/2009

(b)(4)

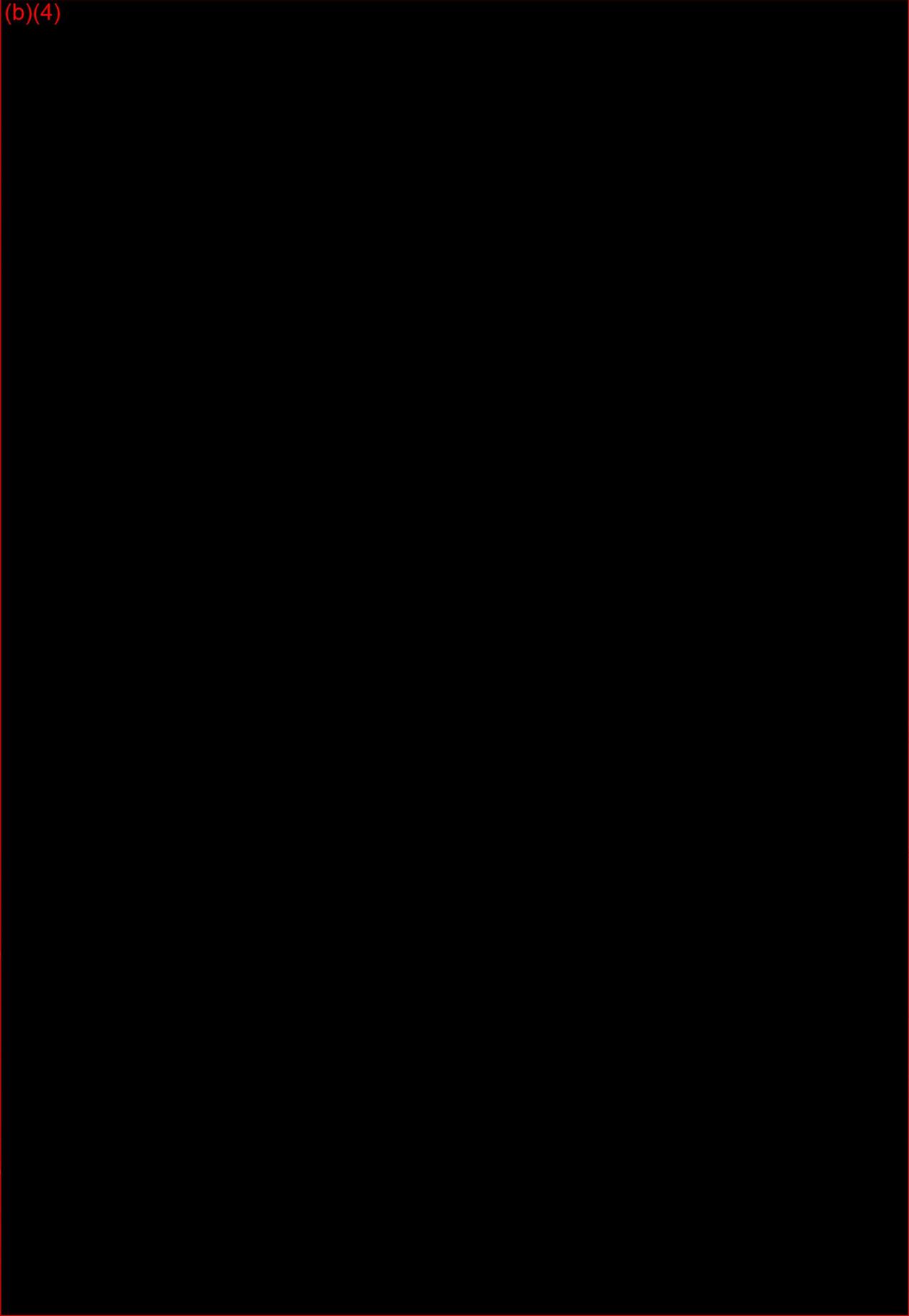


CONFIDENTIAL

Risk Analysis -- Infant Sleep Beanie

Date: 01/04/2009

(b)(4)



CONFIDENTIAL

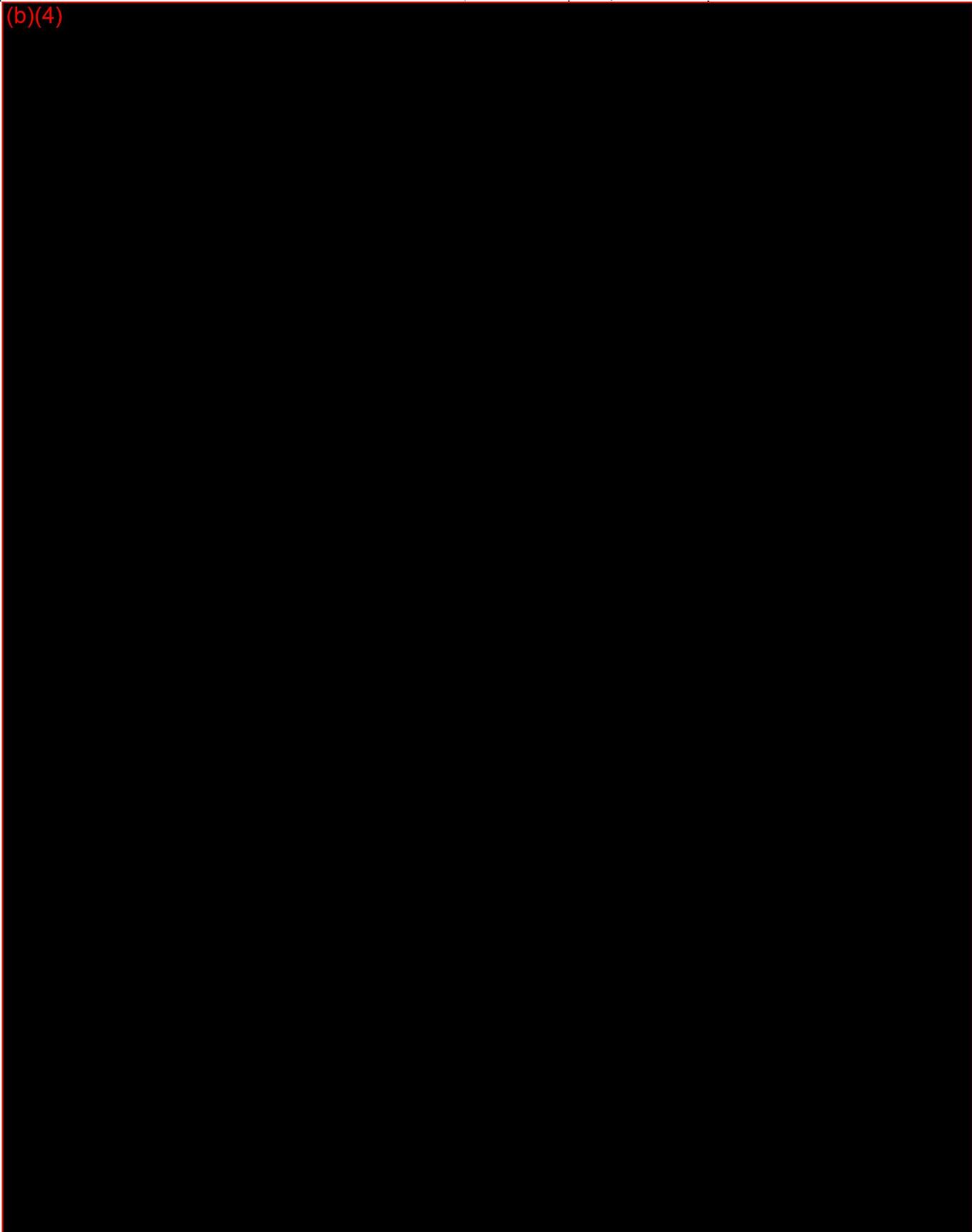
(b)(4)



CONFIDENTIAL

EXHIBIT A

(b)(4)



DRAFT LABELING (revised February, 2009)

**LIFE INNOVATIONS, LLC
INFANT SLEEP BEANIE**

Labeling On Product:

FRONT:

Infant Sleep Beanie

**By Life Innovations, LLC
Wellington, CO**

LOT#

**All New Material
Cotton/Spandex blend/fill
Fiber content: (for example: 50% cotton; 50% lycra)
Exclusive of decoration**

Care on Reverse

Sizing Guide:

(b)(4), Draft

Proper Fit: The Infant Sleep Beanie should conform to the infant's head.

Made in

Distributed by

BACK:

Reg No.:

CARE INSTRUCTIONS:

**Wash prior to first use. Machine wash cold with like colors. Do not bleach.
Tumble dry – low heat**

Hang Tag:

Garment is not flame-resistant and should fit snugly because loose-fitting garments are more likely to catch fire.

125

Labeling

DIRECTIONS FOR USE:

What is the Infant Sleep Beanie?

The Infant Sleep Beanie is a medical device to aid in the prevention of deformational (or positional) plagiocephaly. The Infant Sleep Beanie is intended for healthy, non-ambulating (not yet walking) infants from 0-9 months to aid in the prevention of skull deformation. Its purpose is to deflect the infant's head gently to desirable positions while lying asleep or awake.

Why would I need to use this product?

Positional plagiocephaly is defined as the asymmetry of the skull shape resulting from birthing issues, pregnancy problems, congenital abnormalities and the common positional deformation (flat head). This problem results when young infants are lying in the same position for prolonged periods of time. The incidence of the problem now varies from 13% up to 50% in twins.¹ This condition typically occurs within the first few months of life. Taking precautions to periodically change the position of the infant's head when the infant is lying on his/her back can help prevent a lifelong problem of skull deformity.

Current medical thinking is that the problem has largely evolved out of two lifestyle changes:

- 1) Infants are being placed in carriers, car seats, swings, etc., for prolonged periods of time.
- 2) The 1992 American Academy of Pediatrics (AAP) recommendations for the "back to sleep" program.²

How do I use the Infant Sleep Beanie?

The Infant Sleep Beanie should be placed directly on the infant's head while lying awake, sleeping or during travel. The hat will aid in repositioning the head to multiple different positions as needed with the use of a support roll stitched directly into the seam of the hat.

Change the position of the support roll by adjusting the hat appropriately on the infant's head to either side and to the back. Repositioning is most effective when the infant's head is placed into several positions (right, back and to the left) daily. It is recommended that the infant's head be put into a new position after each use. It is also recommended to periodically remove the hat from the infant and inspect the condition of the infant's head and to

¹ Incidence of Cranial Asymmetry in Healthy Newborns. W. K. Peitsch, C. H. Keefer, R. A. LaBrie and J. B. Mulliken. *Pediatrics* 2002, 110:e72.

² National Institute of Child Health and Human Development, SIDS: "Back to Sleep" Campaign. See: <http://www.nichd.nih.gov/sids/>

check the infant regularly for overheating when the ambient temperature is greater than 90 degrees F.

Avoid placing the infant into the prone position (on the stomach) when the hat is being worn.

It is *NOT* recommended to use the hat when it would interfere with other medical devices.

[ILLUSTRATION]

127

Life Innovations
Limited Liability Company

510(k) SUMMARY

Submitter: Life Innovations, LLC.
Address: P.O. Box 148
Wellington, CO 80549
Phone Number: (208) 420-5059
Fax Number: (208) 734-9941
Contact Person: Jane Y. Scott, M.D.
Chief Executive Officer
Jsco704@aol.com

Date Prepared: February 20, 2009

Device Trade or Proprietary Name: Infant Sleep Beanie
Device Common or Usual Name: Pediatric position holder

Classification: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Panel: General Hospital and Personal Use Devices
Classification: Class I (reserved); GMP Exempt
Classification Code: FRP

Predicate Device(s):

Kozy Comfort™ Infant Positioner	K062143
Head Bed™ Infant Positioner	K060986
Robin Hood Vest™	K051300
Nightform™ Infant Sleep Positioner	K041996

Device Description: The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.

Intended Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (positional) plagiocephaly. The Infant Sleep Beanie is intended for healthy, non-ambulating infants from 0-9 months. Its purpose is to deflect the infant's head gently to desirable positions while lying asleep or awake.

Technological Characteristics: The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled. The Life Innovations Infant Sleep Beanie comes in multiple colors and designs to coordinate with infant clothing.

Performance Summary: The FDA has not established special controls or standards for this device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 02, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

72

K082367/02

*Life Innovations
Limited Liability Company*

April 1, 2009

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

SUBJECT: 510(k) Premarket Notification K082367
Response to Reviewer's Questions
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application was on hold pending receipt of additional information "AI" requested by the Office of Device Evaluation. We submitted a response to the Reviewer's questions on February 25, 2009. On March 3, 2009, the Reviewer phoned with a request for a revised Summary of Safety and Effectiveness and Indications for Use sheet. We provided the revised documents on March 4, 2009. On March 16, 2009, the Reviewer phoned with a request for additional information and put the 510(k) Premarket Notification on hold.

The following additional information is provided in response to the Reviewer's request.

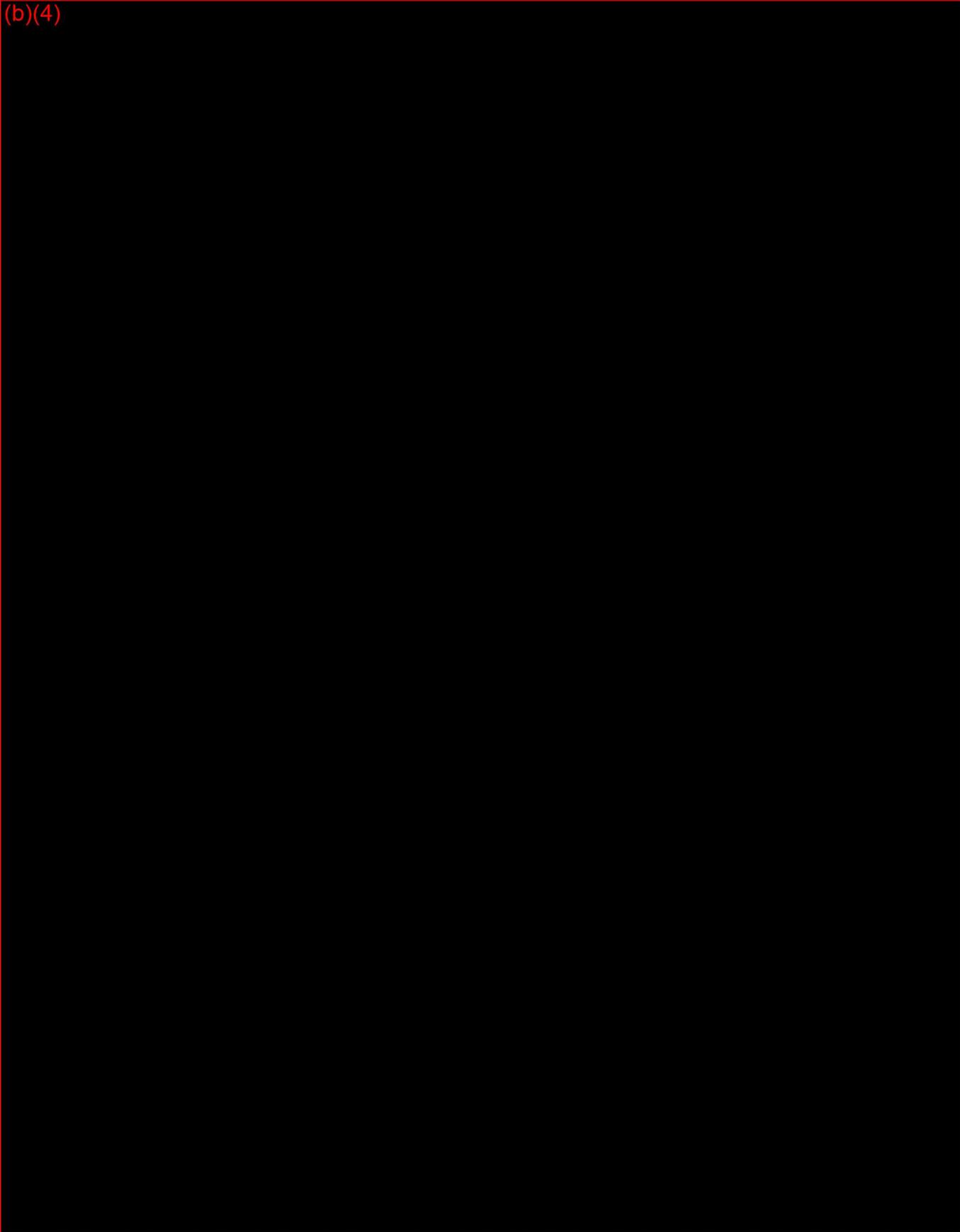
Request 1:

The Reviewer requested that the Indications for Use Statement be inserted in the draft product labeling.

Response: We have revised the labeling accordingly. The revised labeling is provided as an attachment to this response.

Request 2:

(b)(4)



(b)(4)



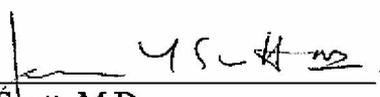
It is respectfully submitted that the Life Innovations Infant Sleep Beanie is substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to a predicate device(s) which is in commercial distribution in interstate commerce.

I would appreciate hearing from you regarding this Premarket Notification at your earliest convenience.

Very truly yours,

Life Innovations, LLC

Signed:


A handwritten signature in black ink, appearing to read "Jane Y. Scott", is written over a horizontal line.

Jane Y. Scott, M.D.
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jsco704@aol.com

Attachments:
Revised Labeling
Appendix A
Appendix B
Appendix C

DRAFT LABELING (revised March, 2009)

**LIFE INNOVATIONS, LLC
INFANT SLEEP BEANIE**

Labeling On Product:

FRONT:

Infant Sleep Beanie

**By Life Innovations, LLC
Wellington, CO**

LOT#

**All New Material
Cotton/Spandex blend/fill
Fiber content: (for example: 50% cotton; 50% lycra)
Exclusive of decoration**

Care on Reverse

Sizing Guide:

(b)(4), Draft



Proper Fit: The Infant Sleep Beanie should conform to the infant's head.

Made in

Distributed by

BACK:

Reg No.:

CARE INSTRUCTIONS:

**Wash prior to first use. Machine wash cold with like colors. Do not bleach.
Tumble dry – low heat**

Hang Tag:

Garment is not flame-resistant and should fit snugly because loose-fitting garments are more likely to catch fire.

77

Labeling

DIRECTIONS FOR USE:

What is the Intended Use of the Infant Sleep Beanie?

The Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly (skull deformation) arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating (not yet walking) infants 0-9 months of age.

Why would I need to use this product?

Positional plagiocephaly is defined as the asymmetry of the skull shape resulting from birthing issues, pregnancy problems, congenital abnormalities and the common positional deformation (flat head). This problem results when young infants are lying in the same position for prolonged periods of time. The incidence of the problem now varies from 13% up to 50% in twins.¹ This condition typically occurs within the first few months of life. Taking precautions to periodically change the position of the infant's head when the infant is lying on his/her back can help prevent a lifelong problem of skull deformity.

Current medical thinking is that the problem has largely evolved out of two lifestyle changes:

- 1) Infants are being placed in carriers, car seats, swings, etc., for prolonged periods of time.
- 2) The 1992 American Academy of Pediatrics (AAP) recommendations for the "back to sleep" program.²

How do I use the Infant Sleep Beanie?

The Infant Sleep Beanie should be placed directly on the infant's head while lying awake, sleeping or during travel. The hat will aid in repositioning the head to multiple different positions as needed with the use of a support roll stitched directly into the seam of the hat.

Change the position of the support roll by adjusting the hat appropriately on the infant's head to either side and to the back. Repositioning is most effective when the infant's head is placed into several positions (right, back and to the left) daily. It is recommended that the infant's head be put into a new position after each use. It is also recommended to periodically remove the hat from the infant and inspect the condition of the infant's head and to

¹ Incidence of Cranial Asymmetry in Healthy Newborns. W. K. Peitsch, C. H. Keefer, R. A. LaBrie and J. B. Mulliken. *Pediatrics* 2002, 110:e72.

² National Institute of Child Health and Human Development, SIDS: "Back to Sleep" Campaign. See: <http://www.nichd.nih.gov/sids/>

check the infant regularly for overheating when the ambient temperature is greater than 90 degrees F.

Avoid placing the infant into the prone position (on the stomach) when the hat is being worn.

It is *NOT* recommended to use the hat when it would interfere with other medical devices.

[ILLUSTRATION]

APPENDIX A

COMMERCIALY AVAILABLE BABY CLOTHES

BABY HAT -- POTTERY BARN

1/20/2015 10:00 AM

Please Select

1/20/2015 10:00 AM

BABY CLOTHES -- PremiesRus p1 of 2

Diaper bag, 2 (17.0) (of 20 products)

Diaper Bag, 2

Little hearts say goodnight to this cute little Sleep Sac. The Sleep Sac is wonderful night time wear, it snaps from neck to toes for easy dressing and diaper changing a snap.

This is a great classic print for any new little boy. Little light gray airplanes fly around this sweet baby face interlock cotton. The Sleep Sac is wonderful night time wear, it snaps from neck to toes for easy...

A little bit of winter wonderland and cute little airplanes fill this soft cotton interlock print. The Sleep Sac is wonderful night time wear, it snaps from neck to toes for easy...

A must have for night time wear, the Sleep Sac has snaps from neck to toes making dressing and diaper changing a snap. This Sleep Sac is made from a warm and fuzzy lightweight fleece.

This Sleep Sac is made from a warm and fuzzy fleece, lightweight fleece which is extra comfy & cozy. A must have for night time wear, the Sleep Sac has snaps from neck to toes.

\$14.95

\$14.95

Please refer to product reviews

Fun and bright are good words to use with this wonderful 100% cotton interlock print. The Sleep Sac is wonderful night time wear, it snaps from neck to toes for easy...

BABY CLOTHES -- PremiesRus p2 of 2

Use keywords to find the product you are looking for.

back to top for each category >



Product

Price

A little bit of winter wonderland and a little bit of penguins fit this soft cotton water lock bootie. This Sleep Sack is wonderful night time wear. It snaps from neck to toes for easy...

\$14.95

Rushia and Lavender Hearts surround the word Phoenix on this print for the newest little princess. The Sleep Sack is wonderful night time wear. It snaps from neck to toes for easy...

\$14.95



Rescue on the red, navy and baby blue print. This nice ribbed knit sleeper, Boldy intended in navy, its print is perfect for the new little one ready to get out and rescue the world!

\$14.95

This sleep sack is made from 100% cotton jersey. The print is a soft washie on a warm navy background. This is a wonderful classic look for the newest baby in your family. The...

\$14.95

Displaying 1 to 10 (of 10 products)

Page 2 of 2

BABY CLOTHES -- The Preemie Store p1 of 3

NOT FOR
SECURE

10/15/15

Search:

Coccoli (14 items)

View

11 - Preemie

Manufacturer



Coccoli Designer Red White Stripes Terry Preemie Footie and hat - fits up to 5-6 lbs
\$22.00



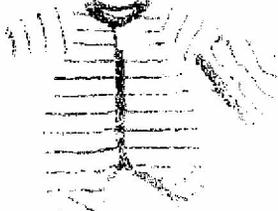
Coccoli Designer Roses Preemie Footie and hat - fits up to 5-6 lbs
\$21.00



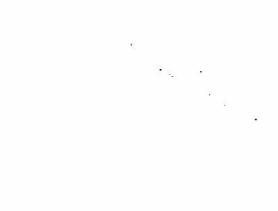
Coccoli Designer Pink Circles Preemie Footie and hat - fits up to 5-6 lbs
\$21.00



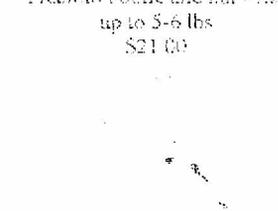
Coccoli Designer Wildflower Preemie Footie and hat - fits up to 5-6 lbs
\$21.00



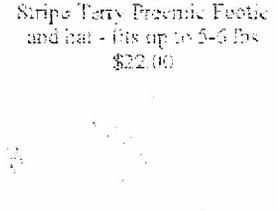
Coccoli Designer Brown Stripes Terry Preemie Footie and hat - fits up to 5-6 lbs
\$22.00



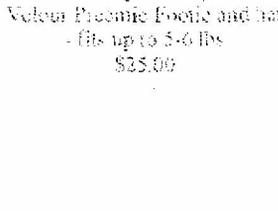
Coccoli Designer Grey Flower Velour Preemie Footie and hat - fits up to 5-6 lbs
\$25.00



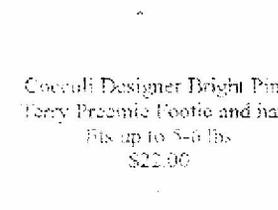
Coccoli Designer Bright Pink Terry Preemie Footie and hat - fits up to 5-6 lbs
\$22.00



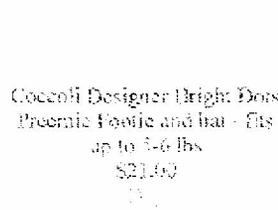
Coccoli Designer Bright Dots Preemie Footie and hat - fits up to 5-6 lbs
\$21.00



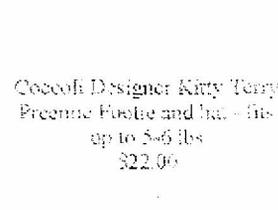
Coccoli Designer Kitty Terry Preemie Footie and hat - fits up to 5-6 lbs
\$22.00



Coccoli Designer Victorian Flower Terry Preemie Footie and hat - fits up to 5-6 lbs
\$22.00



Coccoli Designer Stars Preemie Footie and hat - fits up to 5-6 lbs
\$21.00



Coccoli Designer Red Velour Preemie Footie and hat - fits up to 5-6 lbs
\$25.00

Item C00100234 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100235 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100236 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100237 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100238 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100239 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100240 - Item Title: Preemie Store Blog - (for more information, please email us)

Item C00100241 - Item Title: Preemie Store Blog - (for more information, please email us)

Coccoli Blue Terry Preemie
Boots and hat - fits up to 5-6
lbs.
\$22.00

Coccoli Pink Hearts Preemie
Boots and hat - fits up to 5-6
lbs.
\$22.00

Mailing List

Subscribe to our
Newsletter

Enter your Email
address below and press
the GO button

Subscribe

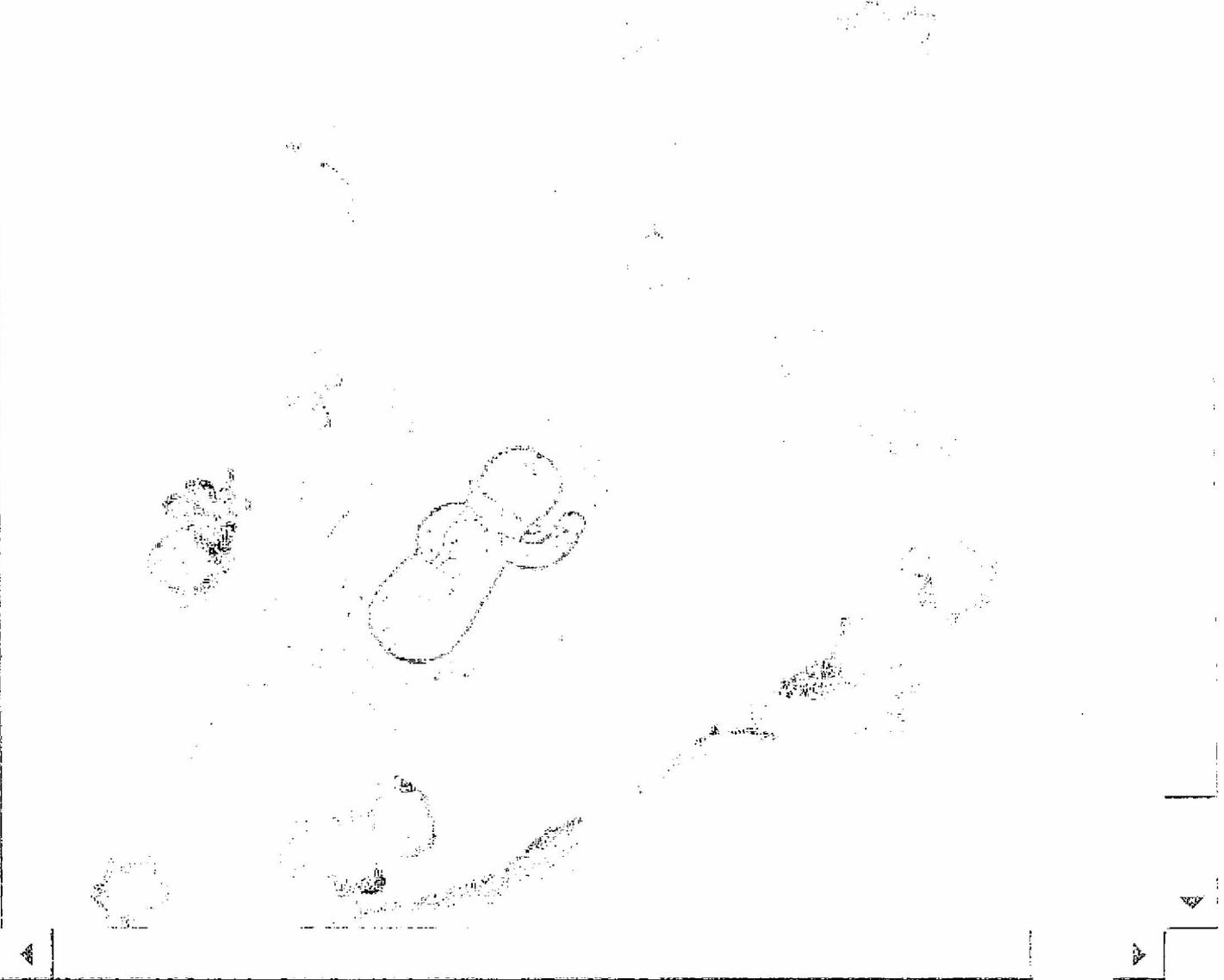
Unsubscribe



Types of mail:
We usually ship by USPS.
If a shipment is computerized and processed via USPS, delivery
times may be subject to change. We reserve the right to ship by
air for expedited shipping. Delivery times may vary. We reserve the
right to ship by air for expedited shipping. Delivery times may vary.



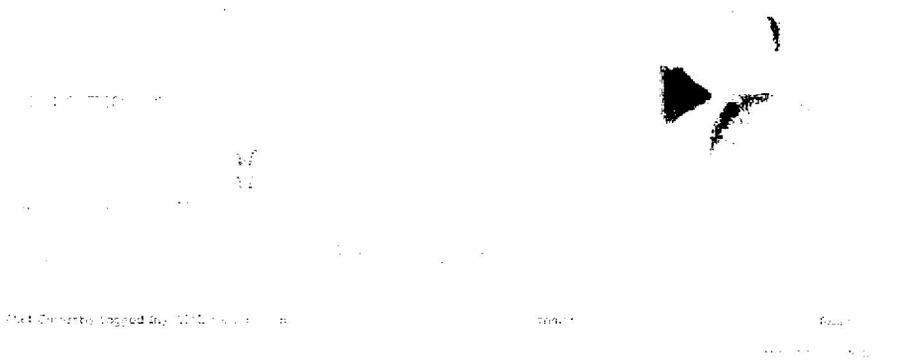
Order placed
on Sunday, 10/25/2014
at 1:07 PM CDT
Your payment is complete. Thank you for your purchase. We will
ship your order as soon as possible.
© 2014 The Preemie Store. All rights reserved. Privacy Policy



APPENDIX B

PREDICATE DEVICES-INFANT POSITION HOLDER

21CFR 880.5680 PEDIATRIC POSITION HOLDER [FRP] Class 1 -- K041996



NightForm Infant Positioning Bed - Baby Blue

Prevent skull flattening in infants and allow them to sleep in safe back - sleeping posture



NightForm Infant Positioning Bed - Pink

Prevent skull flattening in infants and allow them to sleep in safe back - sleeping posture.



NightForm Infant Positioning bed - Special BabyStar Edition

Prevent skull flattening in infants and allow them to sleep in safe back - sleeping posture.

This is a Special Edition NightForm with a cover made by BabyStar of Portland, Oregon. BabyStar makes a beautiful range of baby fabrics that appeal to the design loving parent and the baby's baby ched. NightForm Special Editions are made in limited quantities and aren't repeated. So it's worth it to get it while it's available.



Extra cover set for your Pink NightForm

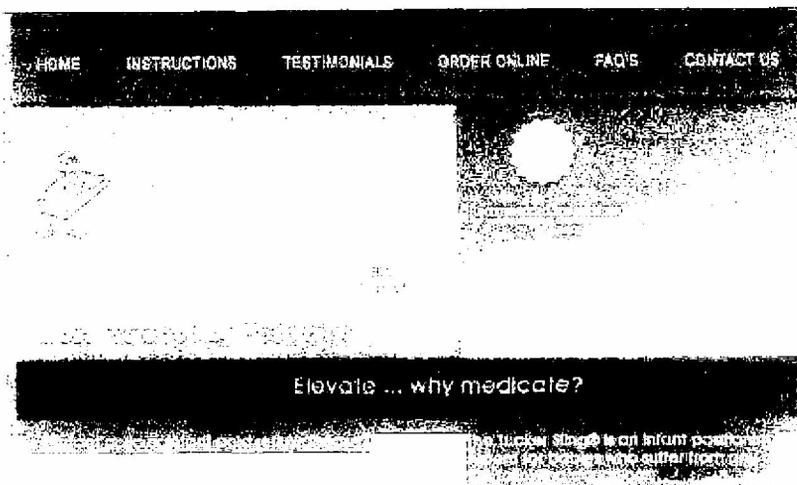
An extra set of covers is helpful to you in managing laundry, or for positioning up all your NightForms. Other place sets include matching cover and two bolster covers.



© Copyright 2005 by Phoenix and Phoenix Products, LLC. All Rights Reserved.

Free Cover Evaluation Form
 Recipient of 2009 Gold Award For
 Best of 3-D models and Accurate
 Research is at covox.com
 Redesigned for 2010. New photos
 & specs at the Official Website.

21CFR 880.5680 PEDIATRIC POSITION HOLDER [FRP] Class 1-K932636



... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.



... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.



The Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

... the Tucker Sling is a safe and effective way to soothe your baby's discomfort. It is designed to provide your baby with a secure and comfortable position that helps to reduce crying and fussiness. The Tucker Sling is made of soft, breathable fabric and is easy to use. It is a great choice for parents who want to soothe their baby's discomfort without using medication.

© Tucker Sling, Inc. 2015

Copyright © 2015 Tucker Sling, Inc. All rights reserved.

APPENDIX C

**PREDICATE DEVICES MADE FROM
FABRICS/TEXTILES**

21CFR890.3640 ARM SLINGS [ILI] Class 1 exempt



Large Plumes w/
Royal Blue Trim -
#SPAL



Bookbinder w/
Plum Trim - #SPAM



Rainbow Diamonds
w/ Khaki Trim -
#SPAG



India Island with
Khaki Trim - #SPAP



Skulls and Roses with
Black Trim - #SPAQ



Autumn Harvest -
#SPAA



Dino Camo -
#SPAT



Green Camo -
#SPAV



Purple Starburst -
#SPAW



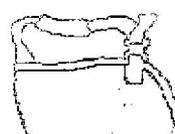
Black Flowers -
#SPAU



Delightful Dots -
#SPAY



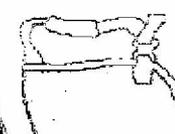
Fabulous Flowers -
#SPAQ



Gothic Harvest -
#SPAX



#SPAD



#SPAD

All Custom Design Logo Dmg Pop It Fashion Arm Slings \$45.95



Custom Logo Sling
with black trim -
#SPAD-1



Custom Logo Sling
with coral brown trim -
#SPAD-2

© 2014 Broken Beauties, LLC. Broken Beauties, LLC. 10000 S. 10th St., Suite 100, Phoenix, AZ 85042
www.brokenbeauties.com
Broken Beauties, LLC. Copyright 2014



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

May 13, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

K082367/S3

*Life Innovations
Limited Liability Company*

May 8, 2009

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

FDA CDRH DMC

MAY 12 2009

Received

SUBJECT: 510(k) Premarket Notification K082367
Response to Reviewer's Questions
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application was on hold pending receipt of additional information "AI" requested by the Office of Device Evaluation. We submitted a response to the Reviewer's questions on February 25, 2009. On March 3, 2009, the Reviewer phoned with a request for a revised Summary of Safety and Effectiveness and Indications for Use sheet. We provided the revised documents on March 4, 2009. On March 16, 2009, the Reviewer phoned with a request for additional information and put the 510(k) Premarket Notification on hold. We responded to the Reviewer's questions on April 1, 2009. On April 10, 2009, the Reviewer sent an email requesting additional information. The FDA letter stating that the Premarket Notification K082367/S002 is on hold was dated April 14, 2009.

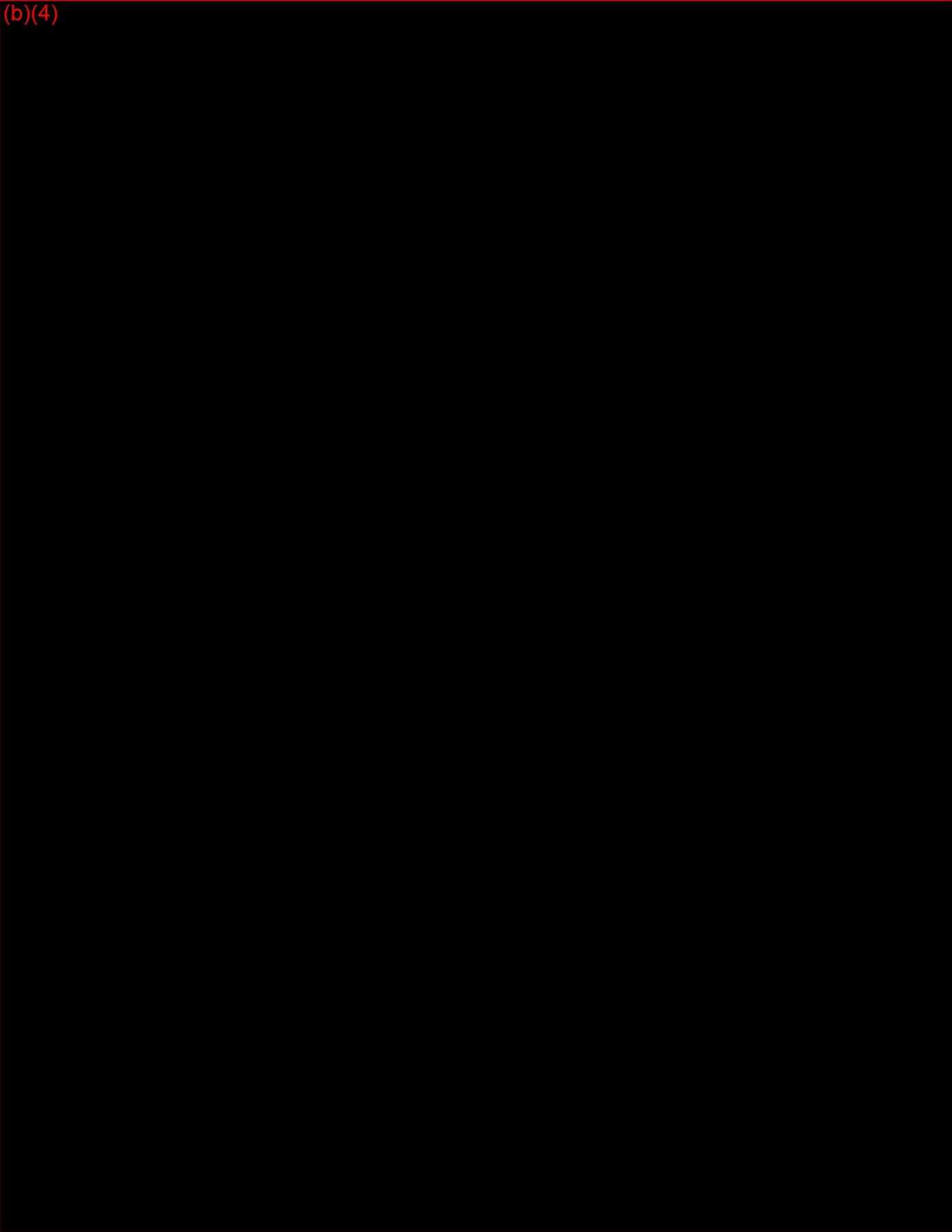
The following additional information is provided in response to the Reviewer's request.

(b)(4)



K250

(b)(4)



(b)(4)

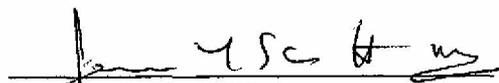
It is respectfully submitted that the Life Innovations Infant Sleep Beanie has the same intended use and technological characteristics (b)(4) as a previously cleared and legally marketed predicate device and does not raise new issues of safety and effectiveness. Accordingly, the Life Innovations Infant Sleep Beanie is substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to a predicate device(s) which is in commercial distribution in interstate commerce.

I would appreciate hearing from you regarding this Premarket Notification at your earliest convenience.

Very truly yours,

Life Innovations, LLC

Signed:



Jane Y. Scott, M.D.
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) 734-9941
Email: Jsc0704@aol.com

Attachments:

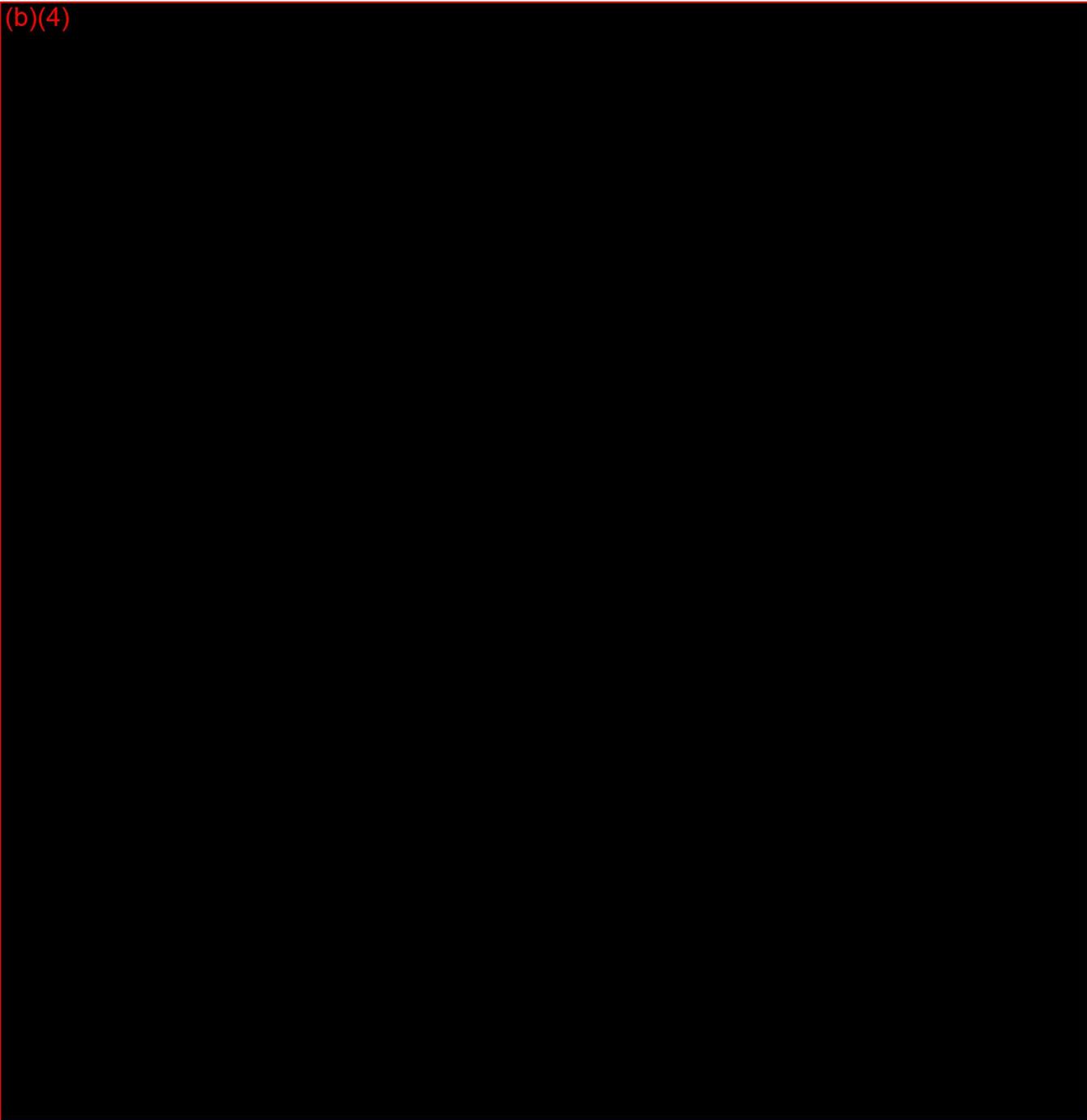
PURCHASING SPECIFICATION
REVISED RISK ANALYSIS
PREDICATE DEVICE INFORMATION
GREEN TEXTILES

CONFIDENTIAL
Life Innovations, Inc. Purchasing Specification
Effective Date: April 15, 2009
Last Revision: April 15, 2009
Page 1 of 2

Purchasing Specification

For

(b)(4)



CONFIDENTIAL

Life Innovations, Inc. Purchasing Specification

Effective Date: April 15, 2009

Last Revision: April 15, 2009

Page 2 of 2

(b)(4)

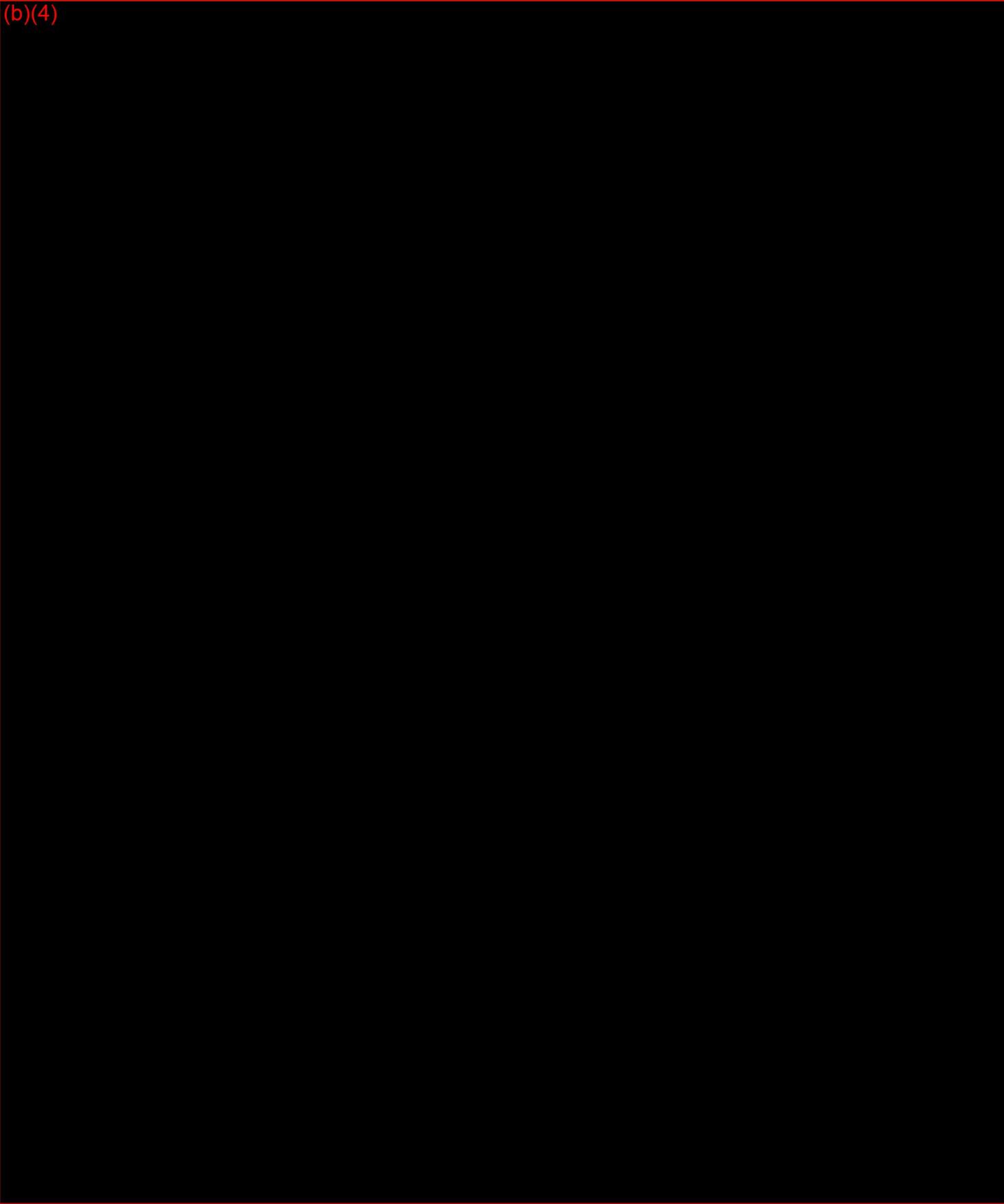


CONFIDENTIAL

Risk Analysis – Life Innovations Infant Sleep Beanie

Date: 01/04/2009 (rev 04/15/2009)

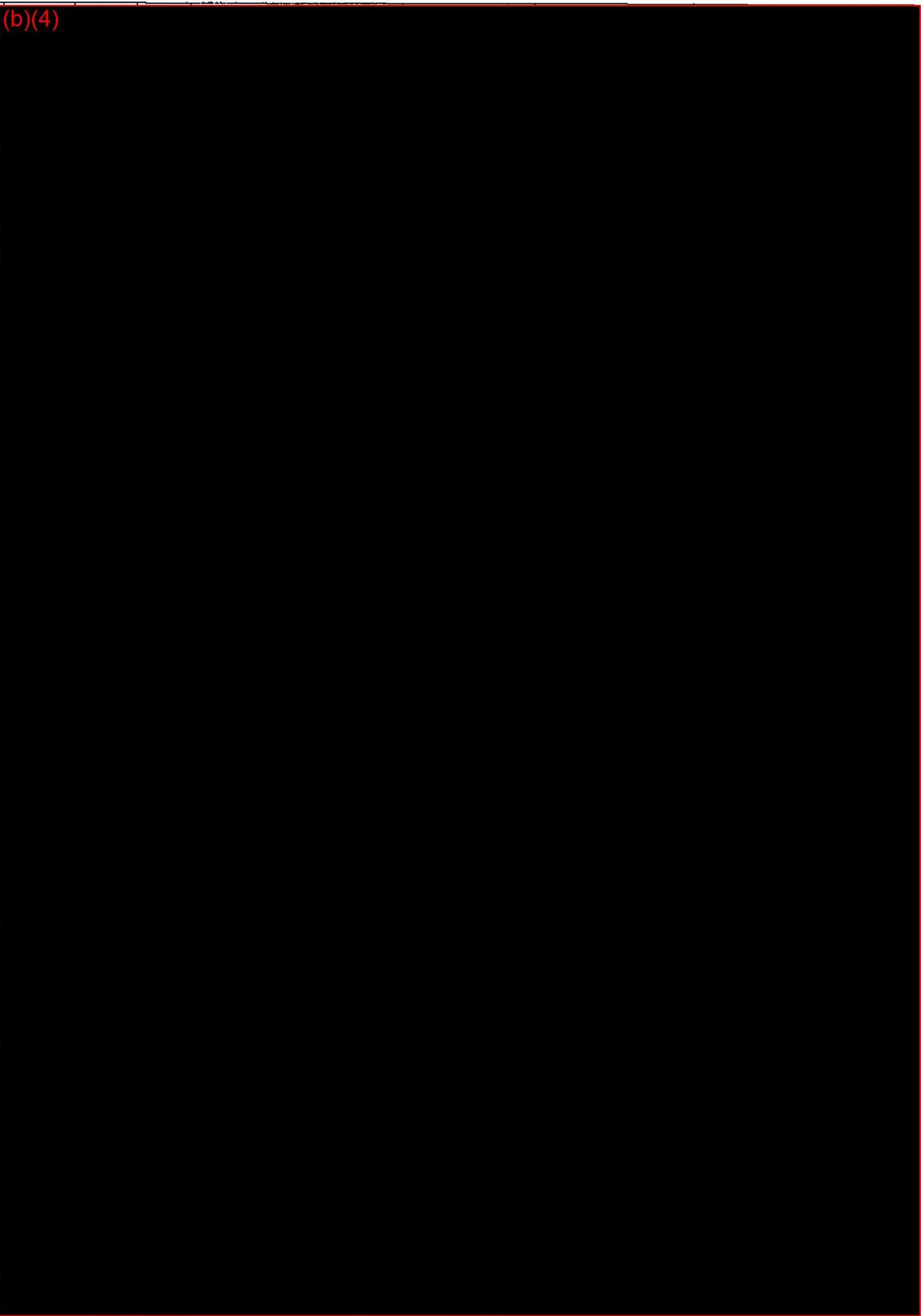
(b)(4)



CONFIDENTIAL

Date: 04/15/2009

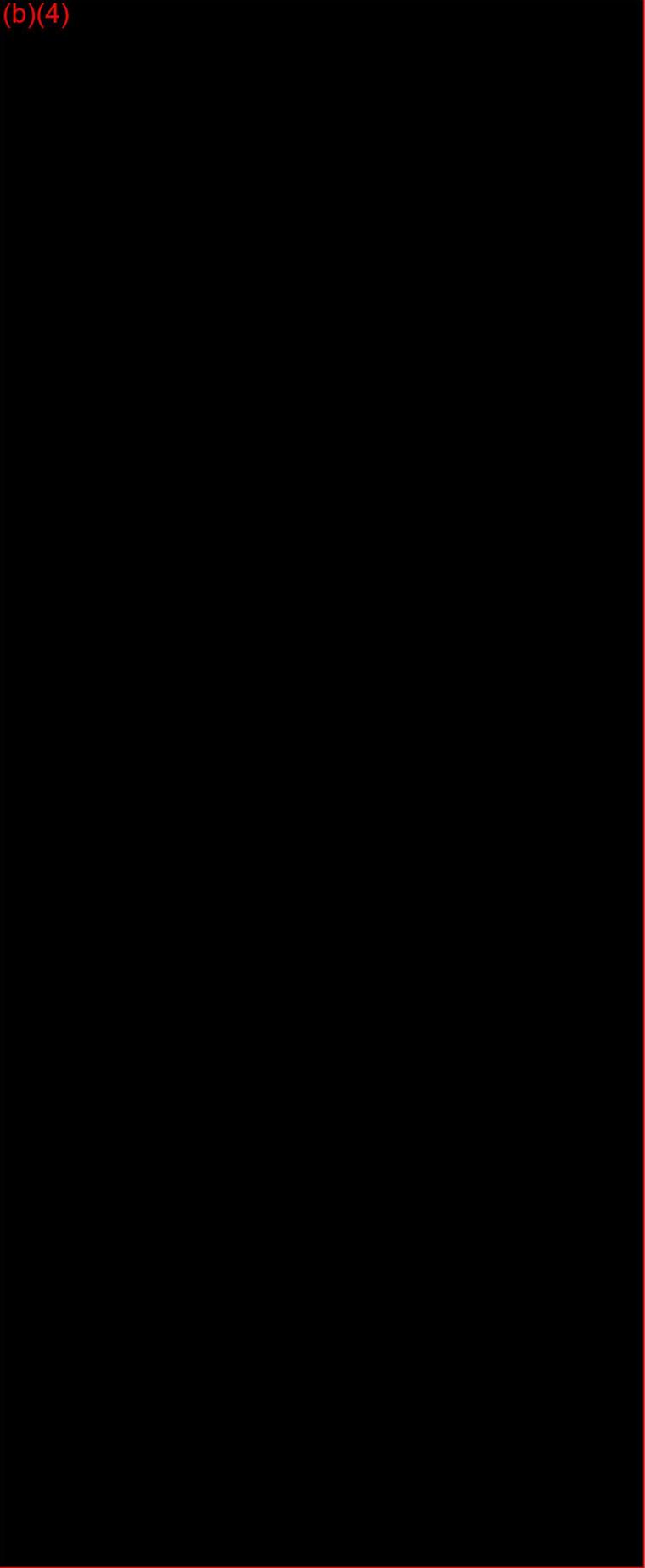
Risk Analysis – Infant Sleep Beanie



(b)(4)

CONFIDENTIAL

(b)(4)



PREDICATE DEVICE INFORMATION

NightForm™ Infant Sleep Positioner

(K041996)

**Product Information to Establish
Substantial Equivalence**

- **NightForm Website with pictures of available products. One product made out of BabyStar fabrics.**
- **About BabyStar fabrics from Website -- Cotton/formaldehyde-free.**
- **NightForm Instructions for Use – Adverse effects: skin irritation.**

http://www.nightform.com/StoreModules/SearchResults.aspx

12/11/2014 10:42:28 AM

24

12/11/2014 10:42:28 AM

12/11/2014
10:42:28 AM

0 items in your shopping cart

(Not Currently Logged In) Click here to login

0 items

Total:

0.00 USD (0.00 USD)



NightForm Infant Positioning Bed - Baby Blue

Prevent skull flattening in infants and allow children to sleep in a safe back - sleeping posture.



Color

Qty: 1



NightForm Infant Positioning Bed - Pink

Prevent skull flattening in infants and allow children to sleep in a safe back - sleeping posture.



Color

Qty: 1



NightForm Infant Positioning Bed - Special BabyStar Edition

Prevent skull flattening in infants and allow children to sleep in a safe back - sleeping posture.

This is a Special Edition NightForm with a cover made by **BabyStar** of Portland, Oregon. BabyStar makes a beautiful range of baby fabrics that appeal to the design loving parent and the texture loving child. NightForm Special Editions are made in limited quantities and aren't repeated. So if you like it, get it while it's available.



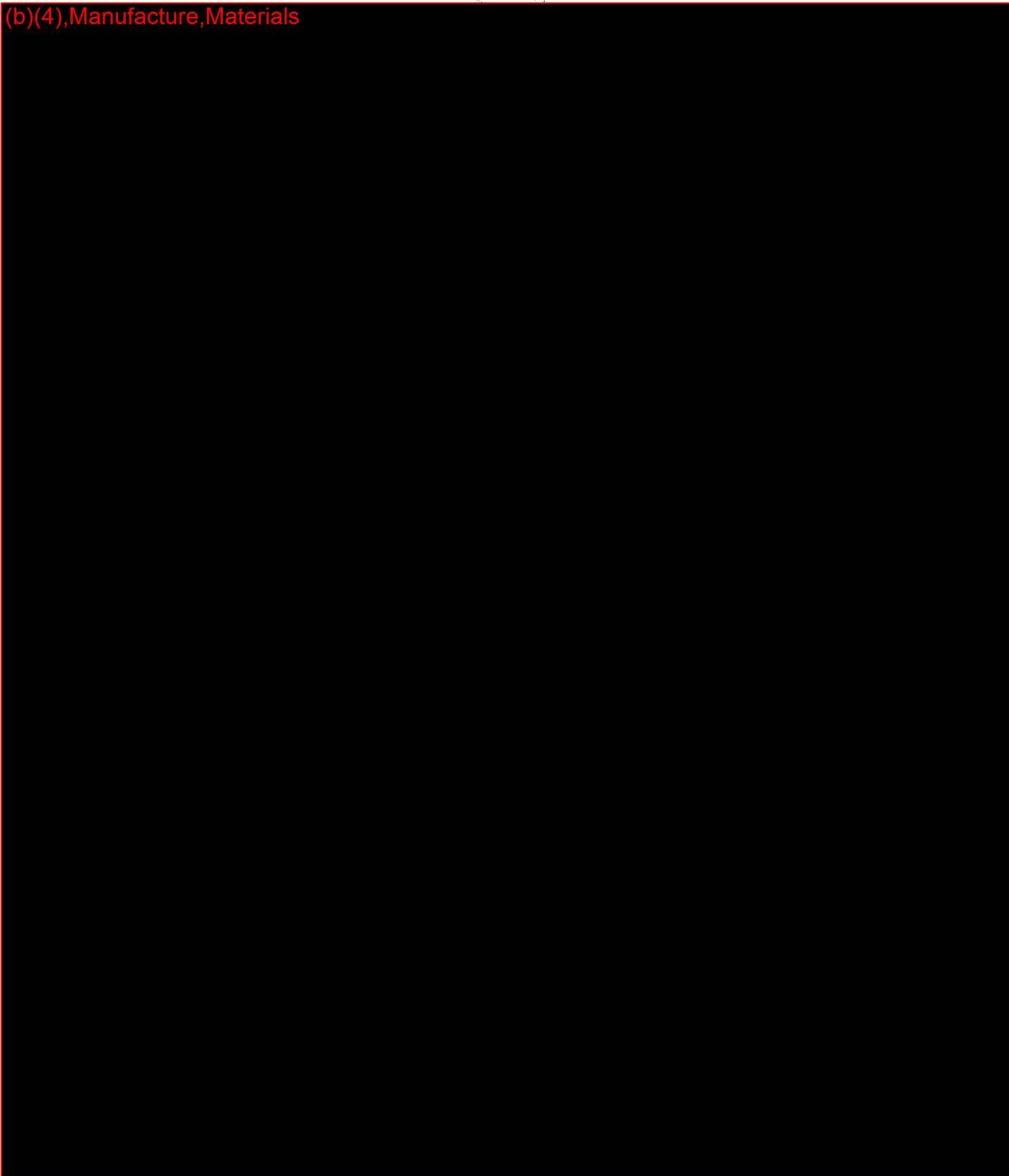
Color

Qty: 1

Extra cover set for your Pink NightForm

An extra set of covers is helpful to you in managing laundry, or

(b)(4), Manufacture, Materials



(b)(4), Manufacture, Materials



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

June 10, 2009

LIFE INNOVATIONS LLC
P.O. BOX 148
WELLINGTON, COLORADO 80549
UNITED STATES
ATTN: JANE SCOTT

510k Number: K082367

Product: INFANT SLEEP BEANIE

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

Life Innovations
Limited Liability Company

K082367/Sy

June 10, 2009

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

FDA CDRH DMC
JUN 10 2009
Received

SUBJECT: 510(k) Premarket Notification K082367
Response to Reviewer's Questions
Type of submission: Traditional
Submitter: Life Innovations, LLC
Device: Infant Sleep Beanie
Classification Name: Infant Position Holder
Classification Code: FRP
Classification: §880.5680 -- Class 1

Dear Sir or Madam:

On August 15, 2008, Life Innovations, LLC submitted a 510(k) Premarket Notification for the Life Innovations Infant Sleep Beanie to the FDA Office of Device Evaluation. On November 7, 2008 we received a letter from your office informing Life Innovations, LLC that review of the application was on hold pending receipt of additional information "AI" requested by the Office of Device Evaluation. We submitted a response to the Reviewer's questions on February 25, 2009. On March 3, 2009, the Reviewer phoned with a request for a revised Summary of Safety and Effectiveness and Indications for Use sheet. We provided the revised documents on March 4, 2009. On March 16, 2009, the Reviewer phoned with a request for additional information and put the 510(k) Premarket Notification on hold. We responded to the Reviewer's questions on April 1, 2009. On April 10, 2009, the Reviewer sent an email requesting additional information. The FDA letter stating that the Premarket Notification K082367/S002 is on hold was dated April 14, 2009. We responded to the Reviewer's questions on May 8, 2009. On May 15, 2009, the Reviewer sent an email requesting additional information and placed the submission on hold.

The following additional information is provided in response to the Reviewer's request.

(b)(4)



174

19

(b)(4)

2. The Reviewer requested an updated 510(k) Summary with the identical Indication for Use statement.

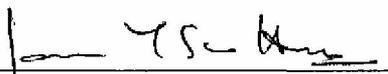
Response: A revised Summary of Safety and Effectiveness is attached with the identical Indications for Use statement.

Accordingly, it is respectfully submitted that the Life Innovations Infant Sleep Beanie has the same intended use and technological characteristics as a previously cleared and legally marketed predicate device(s) and does not raise new issues of safety and effectiveness. The Life Innovations Infant Sleep Beanie is therefore substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to a predicate device(s) which is in commercial distribution in interstate commerce.

I would appreciate hearing from you regarding this Premarket Notification at your earliest convenience.

Very truly yours,

Life Innovations, LLC
Signed:


Jane Y. Scott, M.D.
Chief Executive Officer

P.O. Box 148
Wellington, CO 80549
Phone: (208) 316-5297
Fax: (208) ~~734-9941~~ 733-4902
Email: Jsc0704@aol.com

Attachments:
510(k) SUMMARY rev. June 10, 2009
INDICATIONS FOR USE STATEMENT

Life Innovations
Limited Liability Company

510(k) SUMMARY

Submitter: Life Innovations, LLC.
Address: P.O. Box 148
Wellington, CO 80549
Phone Number: (208) 316-5297
Fax Number: (208) 734-9941
Contact Person: Jane Y. Scott, M.D.
Chief Executive Officer
Jsc0704@aol.com

Date Prepared: June 10, 2009

Device Trade or Proprietary Name: Infant Sleep Beanie
Device Common or Usual Name: Pediatric position holder

Classification: Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Panel: General Hospital and Personal Use Devices
Classification: Class I (reserved)
Classification Code: FRP

Predicate Device(s):

Kozy Comfort™ Infant Positioner	K062143
Head Bed™ Infant Positioner	K060986
Robin Hood Vest™	K051300
Nightform™ Infant Sleep Positioner	K041996

Device Description: The Life Innovations Infant Sleep Beanie is a form fitting infant beanie hat placed strategically on a baby's head while lying awake, sleeping or during travel.

Intended Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Technological Characteristics: The Infant Sleep Beanie is worn on the infant's head and therefore the infant is unable to roll or turn away from the repositioning aid. The Infant Sleep Beanie can be used in all locations – car seat, bouncer, crib, floor stroller, etc. It is a convenient product that is easy to pack and change if soiled.

Performance Summary: The FDA has not established special controls or standards for this device.

Indications for Use

510(k) Number (if known): K082367

Device Name: Infant Sleep Beanie

Indications For Use: The Life Innovations Infant Sleep Beanie is an over-the-counter repositioning device to aid in the prevention of deformational (or positional) plagiocephaly arising from consistent back-sleeping postures. The Infant Sleep Beanie is intended for healthy, non-ambulating infants 0-9 months of age.

Prescription Use _____
(Part 21 CFR §801 Subpart D)

AND/OR

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Life Innovations, LLC
Revised February, 2009