



U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER: (mac)

FOLDER: K073356 - 248 pages

COMPANY: MEDTRONIC MINIMED (MEDTMINIA)

PRODUCT: PUMP, INFUSION, INSULIN (LZG)

SUMMARY: Product: PARADIGM INSULIN INFUSION PUMP, MODELS MMT-512, MMT-712, MMT-515 AND M

DATE REQUESTED: May 10, 2011

DATE PRINTED: May 10, 2011

Note: Printed





Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

APR 25 2008

Re: K073356
Trade/Device Name: Medtronic-MiniMed Paradigm
Model: MMT-512, MMT-712, MMT-515 and MMT-715
Insulin Infusion Pumps
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: April 1, 2008
Received: April 2, 2008

Dear Mr. Faillace:

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

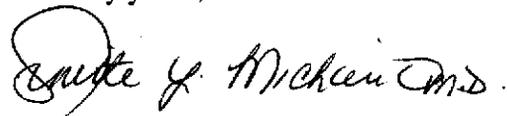
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.
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

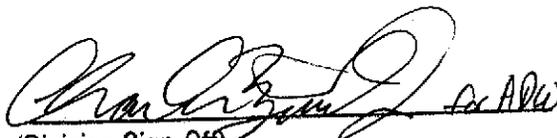
510(k) Numbers: K030531 (MMT-512)
K031390 (MMT-712)
K040676 (MMT-515/MMT-715)

Device Names: Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps

Indications for Use: The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use **AND/OR** **Over-the-Counter Use**
(Per 21 CFR 80 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K073356

Document Cover Sheet:

K073356-K6733

FSR0901-000

Date of Submission:	28-NOV-2007
Description:	PARADIGM INSULIN INFUSION PUMP, MODELS MMT-512, MMT-712, MMT
Date of Scan:	30-MAY-2008
Document Prep:	DSF4 5/30/08
Scanner:	DSF4 5/30/08
Image Quality Reviewer:	



Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Decision Letter 25-APR-2008	1	2	3	<input type="checkbox"/>
Indications for Use 25-APR-2008	3	3	2	<input type="checkbox"/>
Reviewer Memorandum 24-APR-2008	4	5	3	<input type="checkbox"/>
Reviewer Notes 23-APR-2008	6	24	20	<input type="checkbox"/>
SUPP 002 01-APR-2008	25	40	17	<input type="checkbox"/>
Contents 01-APR-2008	25	40	17	<input type="checkbox"/>
Correspondence 26-MAR-2008	41	41	2	<input type="checkbox"/>
Correspondence 25-MAR-2008	42	42	2	<input type="checkbox"/>
Correspondence 31-JAN-2008	43	44	3	<input type="checkbox"/>
Reviewer Notes 30-JAN-2008	45	64	21	<input type="checkbox"/>
SUPP 001 28-DEC-2007	65	89	26	<input type="checkbox"/>
Contents 28-DEC-2007	65	89	26	<input type="checkbox"/>
Correspondence 20-DEC-2007	90	91	3	<input type="checkbox"/>

Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Reviewer Notes 18-DEC-2007	92	101	11	<input type="checkbox"/>
Acknowledgement Letter 07-DEC-2007	102	105	5	<input type="checkbox"/>
Original 28-NOV-2007	106	243	139	<input type="checkbox"/>
CDRH Submission Cover Sheet 28-NOV-2007	106	110	6	<input type="checkbox"/>
Medical Device User Fee Cover Sheet 28-NOV-2007	111	112	3	<input type="checkbox"/>
Cover Letter 28-NOV-2007	113	114	3	<input type="checkbox"/>
Contents 28-NOV-2007	115	129	16	<input type="checkbox"/>
Appendix 1 System Level RF Communications Cover Page 28-NOV-2007	130	130	2	<input type="checkbox"/>
APP 1 Engineering Test Plan 28-NOV-2007	131	138	9	<input type="checkbox"/>
APP 1 Engineering Test Report Contents 28-NOV-2007	139	145	8	<input type="checkbox"/>
APP 1 ETR Appendices 28-NOV-2007	146	243	99	<input type="checkbox"/>
Total documents: 14				<input type="checkbox"/>
Total document pages: 243				<input type="checkbox"/>
Total separator pages: 21				<input type="checkbox"/>
Total Scan pages: 265				<input type="checkbox"/>

QC Signature _____

QC Bar Code Sticker



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

APR 25 2008

Re: K073356
Trade/Device Name: Medtronic-MiniMed Paradigm
Model: MMT-512, MMT-712, MMT-515 and MMT-715
Insulin Infusion Pumps
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: April 1, 2008
Received: April 2, 2008

Dear Mr. Faillace:

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

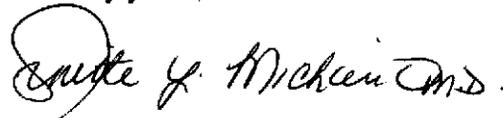
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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) Numbers: K030531 (MMT-512)
K031390 (MMT-712)
K040676 (MMT-515/MMT-715)

Device Names: Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps

Indications for Use: The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use
(Per 21 CFR 80 Subpart D)

AND/OR

Over-the-Counter Use

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073356

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

March 26, 2008

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Device: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515

Extended Until: 29-MAY-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



Medtronic Diabetes
18000 Devonshire Street
Northridge, CA 91325-1219
800-minimed
www.minimed.com

March 24, 2008

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

RECEIVED

MAR 25 2008

1000-1000

RE: K073356: Request For Time Extension

Dear Sir or Madam:

Medtronic MiniMed respectfully requests an extension of an additional 90 days to provide additional information requested for K073356. We had been previously notified by FDA reviewer Charles Zimlicki PhD that this submission had been placed on hold pending receipt of additional information requested via email on January 28, 2008.

Please do not hesitate to contact me via telephone (818-576-5616) or email (mark.faillace@medtronic.com) if you require any additional information or clarification.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark J. Faillace", written over a horizontal line.

Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting

1021⁴²

January 31, 2008

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

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Product: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515

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(1)). 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
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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

December 20, 2007

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Product: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515

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

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

December 07, 2007

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Received: 03-DEC-2007
Product: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515 AND

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

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

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

Please note the following documents as they relate to 510(k) review:
1) 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).
2) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under 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/elecsb.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 Heal

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

November 30, 2007

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Received: 29-NOV-2007
User Fee ID Number: 6033747
Product: PARADIGM INSULIN
INFUSION PUMP,

The Food and Drug Administration (FDA) Center for Devices and-512, 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,

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

K073356

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission November 28, 2007	User Fee Payment ID Number MD6033747-956733	FDA Submission Document Number (if known)
---	--	---

SECTION A TYPE OF SUBMISSION

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Medtronic MiniMed	Establishment Registration Number (if known) 2032227		
Division Name (if applicable)	Phone Number (including area code) (818) 576-5616		
Street Address 18000 Devonshire Street	FAX Number (including area code) (818) 576-6644		
City Northridge	State / Province CA	ZIP/Postal Code 91325	Country USA
Contact Name Mark Faillace			
Contact Title Sr. Director, Regulatory Affairs and Product Reporting		Contact E-mail Address mark.faillace@medtronic.com	

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

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

K20 140 II

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

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

SECTION D2 REASON FOR APPLICATION - IDE

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

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input checked="" type="checkbox"/> Other Reason (<i>specify</i>): Minor labeling change to inform users the pumps can receive glucose values transmitted by a LifeScan OneTouch UltraLink glucose meter.		

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning, safety and effectiveness information	
1	80LZG	2		3		4		<input type="checkbox"/> 510 (k) summary attached	
5		6		7		8		<input checked="" type="checkbox"/> 510 (k) statement	

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K030531	1	Paradigm Model MMT-512	1	Medtronic MiniMed
2	K031390	2	Paradigm Model MMT-712	2	Medtronic MiniMed
3	K040676	3	Paradigm Model MMT-515/MMT-715	3	Medtronic MiniMed
4		4		4	
5		5		5	
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification
 Insulin infusion pump
 Continuous glucose monitor

	Trade or Proprietary or Model Name for This Device		Model Number
1	Paradigm Insulin Infusion Pumps	1	MMT-512, MMT-712, MMT-515, MMT-715
2			
3		3	
4		4	
5		5	

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

1		3		4		5		6
7		8		9		10		11
								12

Data Included in Submission

- Laboratory Testing Animal Trials Human Trials

SECTION G

PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code 80LZG	C.F.R. Section (if applicable) 880.5725	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel General Hospital and Personal Use		

Indications (from labeling)

The Medtronic MiniMed Paradigm insulin infusion pumps are indicated for continuous delivery of insulin, at fixed and variable rates, for the management of diabetes mellitus in persons requiring insulin.

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

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 2032227	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Medtronic MiniMed		Establishment Registration Number 2032227	
Division Name (if applicable)		Phone Number (including area code) 818-	
Street Address 18000 Devonshire Street		FAX Number (including area code)	
City Northridge	State / Province California	ZIP/Postal Code 91325	Country USA
Contact Name Mark Faillace	Contact Title Sr. Director, Regulatory Affairs and Product Reporting	Contact E-mail Address mark.faillace@minimed.com	

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 3004209178	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Medtronic Puerto Rico Operations Co.		Establishment Registration Number 3004209178	
Division Name (if applicable)		Phone Number (including area code) (787) 561-2768	
Street Address road 31, km. 24, hm 4 Ceiba Norte Industrial Park		FAX Number (including area code) (787) 561-2802	
City Juncos	State / Province Puerto Rico	ZIP/Postal Code 00777	Country USA
Contact Name Miguel Beltran Delgado	Contact Title Sr. Quality Systems Manager	Contact E-mail Address miguel.beltran@medtronic.com	

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

SECTION I**UTILIZATION OF STANDARDS**

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

1					
2					
3					
4					
5					
6					
7					

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

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

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

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

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: MD6033747-956733 Write the Payment Identification number on your check.
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:	
<ol style="list-style-type: none"> 1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center. 	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MEDTRONIC MINIMED 18000 Devonshire Street Northridge CA 91325 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 954408171	2. CONTACT NAME Jodie Rogers 2.1 E-MAIL ADDRESS jodie.rogers@medtronic.com 2.2 TELEPHONE NUMBER (include Area code) 818-576-5708 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 818-576-6273
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)	
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice	3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:	
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.	
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)	
<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	

111

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

\$3,404.00

27-Nov-2007

Form FDA 3601 (01-2007)

["Close Window"](#) Print Cover sheet

112



Medtronic Diabetes
 18000 Devonshire Street
 Northridge CA 91325-1219
 800-minimed
 www.minimed.com

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

FDA CDRH DMC

NOV 29 2007

November 28, 2007

Received

Re: Special 510(k): Device Modification – Minor Labeling Change To MMT-512, MMT-712, MMT-515 and MMT-715 Insulin Infusion Pumps To Indicate Ability To Receive Glucose Values Transmitted By The LifeScan OneTouch® UltraLink™ Glucose Meter

Dear Sir or Madam:

Medtronic MiniMed hereby submits this Special 510(k): Device Modification for a minor labeling change to the following previously cleared Medtronic MiniMed Paradigm insulin infusion pumps:

Model number(s)	510(k) Control Number	Date Cleared By FDA
MMT-512	K030531	June 17, 2003
MMT-712	K031390	July 23, 2003
MMT-515/MMT-715	K040676	May 21, 2004

The modifications to these devices are limited to a minor labeling change to indicate that these insulin infusion pumps are capable of receiving glucose values transmitted by the new LifeScan OneTouch UltraLink glucose meter (in addition to the current BD ParadigmLink glucose meter).

Please note that since the LifeScan OneTouch UltraLink meter (b)(4)

(b)(4) there are no changes to the hardware or software of any of these insulin pumps in association with their use with the new LifeScan meter. Additionally, reception of glucose values transmitted from the meter is an optional feature that is provided as a convenience to the pump user (since it eliminates the need to manually enter values for use in the pump's "Bolus Wizard"). Glucose values from any FDA cleared home glucose meter may be used as input for the pump's "Bolus Wizard" and therefore there is no limitation on pump

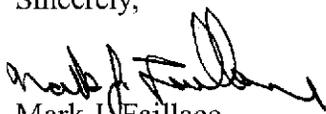
Medtronic MiniMed
Special 510(k) Paradigm Insulin Infusion Pumps

functionality even when used with meters other than the BD ParadigmLink or LifeScan OneTouch UltraLink.

We consider the information contained in this submission to be confidential commercial information and request that it be treated as such by the FDA.

Should you require additional information, please do not hesitate to contact me at (818) 576-5616 or via e-mail (mark.failace@medtronic.com).

Sincerely,



Mark J. Failace

Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed

TABLE OF CONTENTS

SECTION A.	Device Name	4
SECTION B.	Address and Registration	4
SECTION C.	Device Class	4
SECTION D.	Predicate Device Information	5
SECTION E.	Labeling and Intended Use	5
SECTION F.	Device Description and Comparison	6
SECTION G.	Substantial Equivalence	6
SECTION H.	Summary of Design Control Activities	6
SECTION I.	510(k) Statement	6
SECTION J.	Truthful and Accurate Statement	7

ATTACHMENTS

Attachment 1:	New Package Insert
Attachment 2:	Statement of Indications for Use
Attachment 3:	Declaration of Conformity with Design Controls
Attachment 4:	510(k) Statement
Attachment 5:	Truthful and Accurate Statement

APPENDICIES

Appendix 1:	System Level RF Test Protocol and Report
-------------	--

SECTION A. Device Name

The device trade names and common/classification names are:

Device Trade Names	Common/Classification Name
Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 Insulin Pumps	Insulin Infusion Pump, External/ Pump Infusion

SECTION B. Address and Registration

The address and registration of the manufacturing sites for these devices are:

Manufacturing Site	Manufacturing Site
Medtronic MiniMed 18000 Devonshire Street Northridge, CA 91325	Medtronic Puerto Rico Operations Co. road 31, km. 24, hm 4 Ceiba Norte Industrial Park Juncos, Puerto Rico 00777
FDA Registration #: 2032227	FDA Registration #: 3004209178

SECTION C. Device Class

Class: II
Panel: General Hospital and Personal Use Panel: 80
Procode(s): 80LZG
Cite: 21CFR 880.5725

No performance standards have been established for devices of this type under section 514 of the Act; however, the Paradigm insulin infusion pumps listed above have been designed to comply with the following voluntary performance standards:

EN 55011 (CISPR 11): Limits and methods of measurement of radio disturbance characteristics of industrial, scientific, and medical (ISM) equipment;

FCC Part 15; Subpart C: 15.209: Limits for Radiated Emissions;

IEC 60529: Degree of Protection Provided by Enclosures IPX7 Level;

IEC 60601-1: Standard - Medical Electrical Equipment - Part 1: General requirements for safety;

IEC 60601-1-2: Collateral standard for Medical Electrical Equipment - Part 1: General requirements for safety - 712. Electromagnetic Compatibility - requirements and tests;

IEC 60601-1-4: Collateral standard for Medical Electrical Equipment - Part 1: General requirements for safety - 4. Programmable electrical medical systems;

IEC 60601-2-24: Particular requirements for safety of infusion pump and controllers;

IEC 61000-4-2: Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 2: Electrostatic discharge immunity test;

IEC 61000-4-3: Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 3: Radiated, radio-frequency, electromagnetic immunity test;

IEC 61000-4-6: Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 6: Immunity to conducted disturbances induced by radio-frequency fields;

IEC 61000-4-8: Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Section 8: Power frequency magnetic field immunity test;

ISTA Project 2A: Procedure for Testing Packaged Products for Export Shipments, Weighing Under 100 Pounds by the International Safe Transit Association.

SECTION D. Modifications To Previously Cleared Devices

There are no changes to the hardware or software of any previously cleared devices associated with their optional use with the LifeScan OneTouch UltraLink glucose meter. Since the new LifeScan meter uses the same telemetry protocol as the previously cleared BD Paradigm Link Meter, all aspects of communication between Paradigm insulin infusion pumps and the BD Paradigm Link and LifeScan OneTouch UltraLink are identical.

SECTION E. Labeling and Intended Use

Labeling changes are limited to a package insert that will be included with these pumps stating they are compatible with the new LifeScan meter. A copy of this insert is provided as Attachment 1.

There are no changes to the intended use of any Paradigm insulin infusion pumps related to their use with the LifeScan OneTouch UltraLink glucose meter. The statement of indication for use for these devices is provided as Attachment 2.

SECTION F. Device Description and Comparison

The Medtronic MiniMed Paradigm Model model MMT-512, MMT-712, MMT-515 and MMT-715 are:

- External, portable insulin pump that delivers insulin from a reservoir
- Rate programmable and designed for continuous delivery of insulin, at set and variable rates, as prescribed by the user's physician.
- Capable of communicating with a remote programmer or compatible home glucose meters using RF telemetry.

As previously stated, there are no changes to any of these devices except for the minor modification to labeling to indicate that these infusion pumps can receive glucose values from the LifeScan OneTouch UltraLink glucose meter (in addition to the previously cleared BD Paradigm Link meter).

SECTION G. Substantial Equivalence

There are no changes to the hardware, software or indications for use of any Paradigm insulin infusion pumps discussed in this submission and therefore these devices continue to be substantially equivalent to the previously cleared devices.

SECTION H. Summary of Design Control Activities

Design control activities were limited to system level testing conducted to confirm appropriate communication between the Paradigm MMT-522 insulin infusion pump and the LifeScan OneTouch UltraLink glucose meter. The protocol and report for this testing is provided as Appendix 1. Since all Paradigm insulin pumps use identical RF communication hardware and software, this testing is also directly applicable to the MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps.

A Declaration of Conformity with Design Controls is included in Attachment 3.

SECTION I. 510(k) Statement

A 510(k) Statement for the Medtronic MiniMed Paradigm Model 512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps is included in Attachment 4.

SECTION J. Truthful and Accurate Certification

A certification of the truthfulness and accuracy of the information included in this submission is provided as Attachment 5.

Attachment 1: New Package Insert

ATTENTION

This product is compatible with the LifeScan OneTouch® UltraLink™ blood glucose meter.

6025321-011 092607

Attachment 2: Statement of Indication for Use

INDICATIONS FOR USE

510(k) Numbers: K030531 (MMT-512)
K031390 (MMT-712)
K040676 (MMT-515/MMT-715)

Device Names: Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps

Indications for Use: The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use _____
(Per 21 CFR 80 Subpart D)

AND/OR

Over-the-Counter Use _____

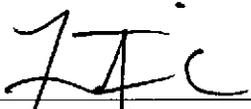
Concurrence of CDRH, Office of Device Evaluation (ODE)

Attachment 3: Declaration of Conformity with Design Controls

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

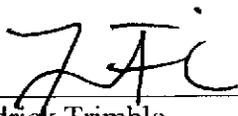


Fredrick Trimble
Vice President, Regulatory Affairs and Quality Assurance
Medtronic MiniMed

November 27, 2007
Date

Manufacturing Facility

The manufacturing facility, Medtronic MiniMed is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



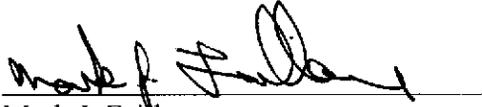
Fredrick Trimble
Vice President, Regulatory Affairs and Quality Assurance
Medtronic MiniMed

November 27, 2007
Date

Attachment 4: 510(k) Statement

510(k) Statement

I certify that, in my capacity as Senior Director of Regulatory Affairs and Product Reporting of Medtronic MiniMed, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the devices described in the premarket notification is determined to be substantial equivalent. This information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



Mark J. Fallace
Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed

11/27/07
Date

Attachment 5: Truthful and Accurate Statement

TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(j), I Mark Faillace, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Senior Director, Regulatory Affairs and Product Reporting of Medtronic MiniMed, and reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device has been knowingly omitted from this submission.



Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting
Medtronic MiniMed

11/27/07
Date

Appendix 1

System Level RF Communications Testing



Medtronic
MINIMED

Doc Type: Z25 Doc Prefix: ETP Doc Number: 07-2282

Category: **Engineering Test Plan**

Doc Description: **LifeScan BG Meter, RF System Testing**

(b)(4)

Pages 46 through 52 redacted for the following reasons:

Exemption 4: These pages contain proprietary test data.



Medtronic
MINIMED

Doc Type: **Z25**

Doc Prefix: **ETR**

Doc Number: **07-2282**

Color

Category: **Engineering Test Report**

Doc Description: **LifeScan BG Meter, RF System Testing**

(b)(4)

Pages 54 through 59 redacted for the following reasons:

Exemption 4: These pages contain proprietary test data.

Appendix A

Cover Sheet, Raw data, Laboratory Notebook 2696, pages 27-29
Laboratory Notebook 2695, pages 61-69 and 2729, pages 80-85

(Total Pages: 19)

Pages 61 through 78 redacted for the following reasons:

Exemption 4: These pages contain raw test data.

Appendix B

Cover Sheet, (b)(4) Test Report (b)(4)

(Total Pages: 10)

Pages 80 through 88 redacted for the following reasons:

Exemption 4: Proprietary Test Data.

Appendix C

Cover Sheet, (b)(4) Report

(Total Pages: 39)

***IN VITRO* STUDY OF THE INTERACTION BETWEEN
WIRELESS PHONES AND AN INSULIN INFUSION PUMP
AND A BLOOD GLUCOSE METER**

**Confidential Study Performed for
Medtronic MiniMed**

EMC REPORT © September 2007a

Pages 91 through 127 redacted for the following reasons:

Exemption 4: Proprietary Test Data.

Appendix D

Cover Sheet, Pumps Rework Travelers and Meters Traceability Documents

(Total Pages: 30)

Note: The 522 and 722 pumps that were used for RF communication testing were previously used in QTR6247 and QTR6248. All those pumps traceability documents can be found in QTR6247 and QTR6248.

Pages 129 through 157 redacted for the following reasons:

Exemption 4: Proprietary Test Data



COVER SHEET MEMORANDUM

From: Reviewer Name Charles Zumbik!
Subject: 510(k) Number K073356/S2
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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE) SE with Limitations, NSE, Withdrawn, etc.).

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

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

Regulation Number 880.5725 Class* Class II Product Code LZ6

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

Additional Product Codes: _____

Review: [Signature] Comp 4/23/08
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 04-24-08
 (Division Director) (Date)

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER K073356-S2

Date: April 22, 2008

From: Charles Zimliki, Ph.D., Diabetes Team Leader (HFZ-480)

Division: DAGID/GHDB

Device Names: Paradigm Model MMT-512
Paradigm Model MMT-712
Paradigm Model MMT-515/MMT-715

Classification: LZG, Infusion Pump, 21 CFR 880.5725, Class II

Company: Medtronic MiniMed
1800 Devonshire Street
Northridge, CA 91325

Contact: Mark Faillace, Senior Director, Regulatory Affairs and Product Reporting
Phone: 818-576-5616, Email: mark.faillace@medtronic.com

Dated: April 1, 2008

Received: April 2, 2008

Recommendation: I recommend that the subject device is **Substantially Equivalent** to the predicate device.

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.
 - Paradigm Model MMT-512 (K030531), LZG, NBW
 - Paradigm Model MMT-712 (K031390), LGZ
 - Paradigm Model MMT-515/MMT-715 (K040676), LZG
 - *Reviewer's note. K031390 appears to have a different product code (i.e., LGZ) than the other two predicate device product codes of LZG. The product code, LGZ is a Warmer, infusion, fluid that is currently unclassified. As this device is not a fluid warmer, I examined the memo of K031390 and I believe it is apparent that the reviewer cleared this device as an infusion pump, but due to typos in the reviewer's memo and the clearance letter, K031390 was cleared under the LGZ product code, which was an error. I believe the appropriate product code for all the predicate devices is LZG.*
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

- Subject Device (K073356, Attachment 2)
 - The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515, and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
- Predicate Device (K030531)
 - The Medtronic MiniMed Paradigm Model MMT-512 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
 - The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening of diabetes mellitus and is not intended for use on neonates. The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.
 - When used together, the BD Paradigm Link Glucose Monitor can automatically telemeter glucose values to the Model 512 insulin pump using radio frequency communication. The glucose value received by the Model 512 insulin pump is used as the default glucose value by the pump's bolus wizard feature if the bolus wizard is used within 12 minutes of the glucose value transmission.
- Predicate Device (K031390)
 - The Medtronic MiniMed Paradigm Model MMT-712 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
- Predicate Device (K040676)
 - The Medtronic MiniMed Paradigm Models MMT-515/MMT-715 insulin pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Discussion (Adequate- Minor changes in Indication): What to do? The sponsor clearly states on page 5 of K073356 that the intended use of their predicate devices have not changed. However, the indication of K030531 is clearly more verbose than the newly proposed indication (above). K030531 appears to contain both the indication of the pump, sensor and sensor/pump system. On December 18, 2007, I spoke with branch chief, Mr. Anthony Watson about this discrepancy and Tony requested I confer with POS (Ms. Rosecrans) to see if that particular predicate device (K030531) would qualify for a special 510(k) application given the proposed indication. Tony also asked me to look at the product labeling of the other two predicate devices having the general indication (K040676 and/or K031390). Tony felt that it might have been possible that application K030531 was the only application that specifically refers to a specific glucose meter in their product labeling. Upon inspection of K040676, I found that the product labeling (Section J, Appendix 3, Part 2) indeed specified a specific blood glucose meter (i.e., BD blood glucose meter) and yet the Agency agreed to allow a general indication to the 510(k) application. Based on this information, Tony and I believe we should allow removal of the specific glucose meter indication from the predicate device and allow the sponsor to have a general indication, which is similar to K031390 and K040676. However, Tony and I believe the sponsor should specify the glucose meter in which they have provided testing (i.e., Lifescan OneTouch Ultralink glucose meter) in their product labeling. This appears to be the precedent that has been established in K031390 and K040676. In addition, I was unable to reach Ms. Rosecrans (12-18-08), but instead, I spoke to Ms. Brandi Stuart of POS and she informed me that the removal of the glucose meter indication from K030531 could still qualify this device for a special 510(k) application since the insulin pump is not technologically different and the BD glucose meter is no longer being manufactured. Brandi believed this change (or removal) of indication is possible in the special 510(k) application realm. Because POS agreed with keeping

this issue within the special 510(k) realm, I believe the removal of the glucose meter indication from the predicate device indication is appropriate provided they detail this information in their product labeling. As the sponsor is clearly identifying communication with the LifeScan OneTouch UltraLink blood glucose meter, I have no concerns with the indication listed for the subject device.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
 - Medtronic MiniMed is submitting this special 510(k) to request clearance for minor labeling changes to Medtronic MiniMed Paradigm insulin pumps (models, MMT-512, MMT-712, & MMT-515/715). The labeling change is limited to informing the users that these devices can receive blood glucose values sent from the LifeScan OneTouch UltraLink blood glucose meter via RF telemetry. Currently, the LifeScan glucose meter is cleared for use (K073231).
 - The sponsor states on page 5 of the application (K073356) that there are no hardware or software changes to any of the previously cleared devices associated with their optional use with the LifeScan OneTouch UltraLink glucose meter. Since the new LifeScan meter uses the same telemetry protocol as the previously cleared BD Paradigm Link Meter, all aspects of communication between the Paradigm insulin infusion pumps and the BD Paradigm Link and LifeScan OneTouch UltraLink are identical.

Discussion (Adequate): This special 510(k) application was the result of branch chief Mr. Anthony Watson and OIVD representative Ms. Patricia Bernhardt's communication with the sponsor. BD is no longer producing the glucose meter in which had communication privileges with the Paradigm insulin pumps. Through multiple conversations with Medtronic, the Agency informed Medtronic that a special 510(k) submission would be needed to modify the labeling of the infusion pumps that have 510(k) clearance (i.e., models MMT-512, -715, -515, & -715) and a PMA supplement would be needed for infusion pumps that are approved under P980022 (i.e., models MMT-522 & -722). Therefore, this special 510(k) application is in conformance with the Agency's recommendation and the modifications made to the Paradigm models (MMT-512, -715, -515, & -715) is appropriate for a special 510(k) application.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.
 - Labeling
 - The sponsor states on page 5 that labeling changes are limited to a package insert that will be included with these pumps stating they are compatible with the new LifeScan meter. A copy of this insert is provided in Attachment 1 (K073356).
 - Intended Use (K073356, Attachment 2)
 - Physical Characteristics Identical to previously cleared predicate devices.

Discussion (Adequate): In the original submission, K073356, the sponsor added the LifeScan glucose meter to their product labeling without providing information about the glucose meter and/or communication testing. The sponsor informed me, at that time, the glucose meter was under review and was not cleared (K073231). Since the glucose meter was currently under review, the subject device could not be cleared since it is communicating with the glucose meter and this application did not have any information relating to the safety and effectiveness of the glucose meter. This issue has been expressed clearly to Medtronic on a number of telephone conversations in which they have acknowledged this concern and this was confirmed with our advisory in deficiency #3 of K073356. In discussions with branch chief Mr. Anthony Watson, he indicated that there is an Outstanding device letter that may be appropriate, but upon reading the outstanding device boilerplate letter, it appears the sponsor has only 30 days to respond without the

option of extension before the application is withdrawn/deleted. I brought this to the attention of 510k staff director, Ms. Heather Rosecrans who informed me that this outstanding device letter was intended to be used for devices that needed a clinical study and acquiring these results would take much longer than the 6 month extension the Agency gives to 510k applicants. Ms Rosecrans informed me that she thought the outstanding device letter would not be appropriate in this instance. Instead, since the application was submitted after 10-2-07, we are allowed to place the application on hold for more than 2 rounds before making a final recommendation. She recommended that we continue to place the device on hold for labeling their device with a device that is not a legally marketed device. This deficiency would be an outstanding deficiency until the glucose meter is cleared. This deficiency was used in each of the previous Telephone hold decisions in K073356 & K073356/S1. On 4-17-08, K073231, the Lifescan OneTouch Ultralink glucose meter was cleared. Since the glucose meter was cleared, the subject device can label communication privileges with another cleared device and my concerns have been adequately addressed.

5. A Design Control Activities Summary which includes:

A Design Control Activities Summary (DCAS) was provided by the sponsor (p. 6, K073356).

a) Risk Analysis

- Risk analysis was performed in accordance with (b)(4)

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

- The sponsor provided a DCAS table in K073356/S2 (p. 3)

Discussion (Adequate): In the original submission, the sponsor did not provide a DCAS table nor did the sponsor identify the risk analysis method used to generate their design control activity summary. The sponsor has only indicated that they have performed a system level analysis. I have been informed by Heather Rosecrans of POS that we are unable to review data/experimental reports in a special 510(k) application so I informed the sponsor that I could not evaluate the adequacy of their reports in a special 510(k) application and if they wanted to keep this as a special 510(k) application, they would need to provide a design control activity summary table in their application. The sponsor informed me on 12-17-07 that they were not aware that I could not review test reports in a special 510(k) application, but they would still like to be a special 510(k) application. Therefore, I informed the sponsor that I would be placing their application on hold and they should be receiving my concerns via email shortly. In addition to the DCAS, I also believe the sponsor should clearly show how the communication of the new LifeScan OneTouch UltraLink blood glucose meter is compatible with the Paradigm infusion pumps in their DCAS table.

In K073356/S1, the sponsor identified the risk method as being in accordance with (b)(4) thereby clarifying this issue. The sponsor also provided a DCAS table with only one risk associated with the modification, "pump displays incorrect meter readings". This is certainly a risk that needs mitigation, but the sponsor submitted EMC testing in K073356 that addresses a number of other risks (i.e., interference, immunity, etc.) that the sponsor needs to incorporate into their DCAS table. In addition, the sponsor has conducted testing on a glucose meter that is not cleared and the Agency believes testing should be performed on final finished devices. Since this testing within the DCAS table may not be appropriate because the glucose meter is not cleared, the sponsor needs to address this concern. Last, the sponsor has identified the LifeScan OneTouch Ultralink blood glucose meter in which their pumps communicate with. However, as stated above, this glucose meter is not cleared and therefore not a legally marketed device. In a discussion with 510k staff director, Ms. Heather Rosecrans on 1-18-08, she indicated that product labeling cannot include communication privileges with devices that are not legally marketed. Since the meter is currently not a legally marketed device because it has not received clearance, the sponsor cannot claim communication privileges with this uncleared medical device.

In K073356/S2, the glucose meter, K073231, the Lifescan OneTouch Ultra meter has been cleared (4-17-08) and the sponsor has sent an email received 4-21-08 indicating that the RF testing (i.e., communication testing) between the subject device pump and the OneTouch meter was performed on an identical version of the cleared OneTouch glucose meter. Since the testing provided in the DCAS table is now valid, I asked Sajjad Syed to review the EMC testing

that was provided in the DCAS table. Mr. Syed believed there was sufficient design controls to suggest the communication testing was adequate. As such, the sponsor has provided the appropriate testing that suggests the subject device pump can communicate adequately with the cleared glucose meter, K073231. Therefore, the information is adequate.

- c) Declaration of conformity with design controls. The declaration of conformity should include:
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
 - Found in K073356, Attachment 3
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
 - Found in K073356, Attachment 3

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

- Truthful and Accuracy Statement – K073356, Attachment 5
- 510(k) Statement – K073356, Attachment 4
- Indication for Use page – K073356, Attachment 2

Contact History

4-17-08 Received email from sponsor indicating K073231 (LifeScan glucose meter) was cleared by the Agency.

4-18-08 Received email indicating the RF communication testing described in the DCAS table was performed on the cleared device and the subject device.

4-21-08 Clarification of 4-18-08 email. Sponsor reference incorrect 510k number in the 4-18-08 email. Sponsor stated K073261 in the 4-18-08 email, but the sponsor corrected their statement indicating that they meant to use the following 510k number, K073231.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision:

Note: See

http://erom.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:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
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:

K073356 Deficiencies

The sponsor must provide additional information for me to determine if the subject device is substantially equivalent to the predicate devices.

1. The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns.

- a. Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g., EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Control Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.

Sponsor's Response

As indicated in our original submission, there are no hardware or software changes to Paradigm insulin infusion pumps related to their use with the new LifeScan OneTouch UltraLink glucose meter since the new LifeScan meter was developed using the same RF telemetry specification used in the previously cleared BD Paradigm Link meter. Since there were no hardware or software changes to any Medtronic MiniMed devices, design control activities focused on confirmatory system level testing conducted using Paradigm insulin infusion pumps in combination with LifeScan OneTouch UltraLink meters. These verification activities are summarized in the table (p. 2, K073356/S1).

Discussion (Additional Info Required): The sponsor has provided a DCAS table on page 2 of K073356/S1. However, the sponsor provided a general summary of the testing they performed on the device system. I only know this because in the original submission of K073356, the sponsor provided testing in which the Agency informed them we could not review unless they wanted to convert their application from a special to a traditional 510k application. Since the sponsor did not want to convert the submission to a traditional, the sponsor is required to provide a DCAS table that identifies the risks associated with communicating with a new glucose meter. The sponsor is correct in that there are no design changes to the pump, but since the sponsor is claiming that the pump is communicating with another medical device (i.e., LifeScan OneTouch Ultralink), the system does have other risks associated with the system (e.g., risk of interference, immunity, or the pump displays incorrect meter information, etc.). These risks should be documented in the DCAS table. The sponsor appears to only have provided a very generalized description and does not clearly identify the risks associated with adding a new glucose meter device to the system. Clearly there are risks associated with adding a meter to the system or the sponsor would not have submitted bench testing data in their original application. In addition, the sponsor has stated in their risk analysis that they have identified the risks in accordance to (b)(4). The risks associated with this standard should be incorporated into their DCAS table. Also, the sponsor has clearly identified verification activities by confirming that "appropriate" communication occurs between the pump and the new meter, but the sponsor does not identify what they believe is appropriate communication. It is apparent that appropriate communication is important since the meter reading can be used for insulin dose adjustments. Last, the acceptance criteria only specified that the glucose meter can communicate with the pump in eight different directions as the only acceptance criteria, but the sponsor did not specify any type of acceptance criteria with respect to interference, immunity, etc. I believe the generalized DCAS table provided by the sponsor is grossly inadequate in that it does not identify the risks associated with adding a new glucose meter device to communicate with the pump. I recommend deficiency #1 in K073356/S1 deficiencies.

- b. In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.

Sponsor's Response

The RF protocol used in the BD Paradigm Link and the LifeScan OneTouch UltraLink glucose meters is described in the software requirements specification (ES9411) provided in Attachment 1. This specification was provided to LifeScan by Medtronic MiniMed prior to their development of the OneTouch UltraLink glucose meter and served as the basis for LifeScan's development of the new meter's RF hardware and software. The successful completion of the system level communications testing confirmed that the new LifeScan meter successfully implements this telemetry protocol. Additional details regarding verification testing performed by LifeScan to confirm that the OneTouch UltraLink meter complies with all specified requirements are provided in the 510(k) submitted by LifeScan K073231 for the OneTouch UltraLink meter.

Discussion (Adequate): The sponsor has provided the communication specifications of the pump and believes their system level testing proves the meter and pump communicate properly. I believe that if the sponsor adequately describes all the system level testing that the sponsor has performed that this is sufficient data. Since I have asked for a detailed DCAS table above, I believe this concern will be addressed with such a DCAS table. I have no additional concerns.

- c. As part of your DCAS table, please identify what risk analysis (e.g., FMEA) was used to analyze the risk associated with your device/labeling modification.

Sponsor's Response

The analysis of risks associated with our labeling modification to indicate compatibility with the LifeScan OneTouch UltraLink meter was conducted in accordance with (b)(4). This analysis is documented in an engineering report and is provided as Attachment 2 of this submission for your reference.

Discussion (Adequate): The sponsor has provided a risk analysis that should be incorporated into their DCAS table. I am unsure why they did not incorporate this information into the table. As I have already asked for a detailed DCAS table, I believe the risks associated in Attachment 2 will be included in the DCAS table. Since the sponsor said their risk analysis is in accordance with (b)(4) (b)(4) the sponsor has identified the risk analysis method for their device. As such, I have no additional concerns.

2. You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e., LifeScan OneTouch Ultralink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.

Sponsor's Response

We currently only intend to label our insulin pumps to indicate they are capable of receiving glucose values transmitted by the BD Paradigm Link meter and the new LifeScan OneTouch UltraLink meter. The statement in our original submission indicating that "Glucose values from any FDA cleared home glucose meter may be used as input for the pump's "Bolus Wizard" and therefore there is no limitation on pump functionality even when used with meters other than the BD Paradigm Link or LifeScan OneTouch UltraLink" is referring to the fact that a glucose value calculator. However, at this time, there are no other meters that will be marketed in the United States that will included the ability to transmit glucose values via RF to Paradigm infusion pumps.

Discussion (Adequate): The sponsor has clearly stated that the only two meters for which their pump can receive glucose meter readings are from the BD Paradigm Link or the LifeScan OneTouch UltraLink glucose meter. The sponsor has specifically identified the only two meters for which this pump can be used. Therefore, I believe the sponsor has provided adequate information.

3. You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch Ultralink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that your application containing your labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.

Sponsor's Response

We understand and acknowledge that our special 510(k) can not be cleared until FDA has cleared the LifeScan 510(k) for the OneTouch UltraLink glucose meter.

Discussion (Additional Info Required): The sponsor has acknowledged that the subject device cannot be cleared prior to the clearance of the LifeScan OneTouch Ultralink blood glucose meter. I have discussed the LifeScan OneTouch Ultralink blood glucose meter review (K073231) with the OIVD lead reviewer, Ms. Patricia Bernhardt on Friday 1-18-08 and she informed me that K073231 is still under review and the application will be put on hold for additional information. Since the glucose meter is currently uncleared, the subject device cannot be cleared. This issue has been expressed clearly to Medtronic on a number of telephone conversations in which they have acknowledged this concern and was confirmed with our advisory above, so I am unsure why the sponsor would rapidly respond (application placed K073356 on hold 12-18-07, response received 12-28-07) to my additional

information request when the glucose meter that they intend to communicate with does not have clearance. In discussions with branch chief Mr. Anthony Watson, he indicated that there is an Outstanding device letter that may be appropriate, but upon reading the outstanding device boilerplate letter, it appears the sponsor has only 30 days to respond without the option of extension before the application is withdrawn/deleted. I brought this to the attention of 510k staff director, Ms. Heather Rosecrans who informed me that this outstanding device letter was intended to be used for devices that needed a clinical study and the results of this study would take much longer than the 6 month extension the Agency gives to 510k applicants. Ms Rosecrans informed me that she thought the outstanding device letter would not be appropriate in this instance. Instead, since the application was submitted after 10-2-07, we are allowed to place the application on hold for more than 2 rounds before making a final recommendation. She recommended that we continue to place the device on hold for labeling their device with a device that is not a legally marketed device. This deficiency would be an outstanding deficiency until the glucose meter is cleared. Last, from discussions with Ms. Rosecrans, it occurred to me that the testing the sponsor has detailed in the DCAS table may not be appropriate since the sponsor is conducting testing with an uncleared glucose meter. The Agency has a long history of requiring bench testing on products that are on the final finished device. As the glucose meter is not cleared, the sponsor cannot guarantee that the testing evaluating the communication between the meter/pump has been performed on the final finished device. As such, I believe the sponsor should certify that the testing performed on the meter/subject device are both on the final finished device. I recommend deficiency #2 in K073356/S1 deficiencies.

K073356/S1 Deficiencies

1. You have provided a Design Control Activities Summary (DCAS) table that identifies only one risk with your device and the LifeScan OneTouch UltraLink glucose meter (i.e., pump displaying different glucose value than the glucose meter). However, the Agency believes there are additional risks that you have not incorporated into your DCAS table that should be included. For example, the Agency believes there are Electromagnetic Compatibility (EMC) concerns that your device may not communicate properly with the LifeScan OneTouch UltraLink glucose meter. Presumably, you have tested the communication of your pump with the LifeScan OneTouch UltraLink glucose meter for example interference or immunity using a variety of phones, metal detectors, household emitters, etc. that mitigates such EMC concerns. This type of testing must be incorporated into your DCAS table with each test having their own specific risk and acceptance criteria that allows you to mitigate the identified risk. In addition, you have stated that you have performed a formal risk analysis according to ISO 14971, please incorporate those risks and their corresponding verification activity, acceptance criteria, and results of verification into your DCAS table that allows you to claim communication compatibility of your pump with the LifeScan OneTouch UltraLink glucose meter.

Sponsor's Response

The sponsor states that their insulin pump is unchanged and uses the identical communication protocol that was approved in their own predicate devices. The sponsor feels that there would be no reason to suspect any difference in RF communication. Despite the fact that the sponsor feels there is no reason to suspect differences in RF communication, the sponsor submitted an updated DCAS table on page 3 of K073356/S2. The updated DCAS table included system level testing between the Paradigm pump and the LifeScan OneTouch UltraLink glucose meter. The testing included exposing the system to radiated RF fields, power frequency magnetic fields, EAS equipment, cell phones, cordless phones, metal detectors, microwave ovens, and wireless networks during active meter/pump communication. The sponsor believes the results of this testing are consistent with the previous system level testing when using the BD Paradigm Link, which was previously cleared for use with these insulin pump models.

Discussion (Adequate): The sponsor has submitted an updated DCAS table that describes the types of testing used to evaluate the adequacy of the communication. I have asked Mr. Syed to review the adequacy of the EMC testing and it was his opinion that the description of the communication and the testing described in the DCAS table is sufficient information to establish the safety and effectiveness of the device.

2. You have indicated that the Paradigm pump models MMT-512, -712, -515, and -715 are to communicate with the LifeScan OneTouch Ultralink blood glucose meter. However, the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter as being a legally marketed device. Please address the following concerns.

- a. The Agency believes your device product labeling can only identify communication with medical devices that have been Agency cleared. Please provide the 510(k) numbers of all medical devices with which your pump models are labeled to communicate with.

Sponsor's Response

The sponsor clarified that the Paradigm insulin pump models MMT-512, -715, -515, and -715 have already been previously cleared with the BD Paradigm Link glucose meter. However, the sponsor acknowledges that their device cannot be cleared prior to clearance of the LifeScan OneTouch UltraLink glucose meter.

Discussion (Adequate): On February 17, 2008, the LifeScan OneTouch UltraLink glucose meter was cleared by the Agency allowing communication between the sponsor's subject devices and this glucose meter. Since the glucose meter has been cleared, I believe this issue has been resolved.

- b. You have provided a DCAS table that identifies testing of your pump with the LifeScan OneTouch Ultralink blood glucose meter. The Agency believes testing of your device with other medical devices should be performed on final finished devices for every device. Since the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter being a legally marketed device, bench testing with this device cannot be performed on the final finished device. Please update your DCAS table to include testing of your device with only legally marketed (i.e., final finished device) blood glucose meters that you intend to communicate with (i.e., LifeScan OneTouch Ultralink blood glucose meter). Please certify that all testing described in the DCAS table are on final finished devices.

Sponsor's Response

The sponsor clarified that in most cases, the designs of new medical devices are finalized and validated prior to submission of the 510k application. Therefore, testing of the LifeScan OneTouch UltraLink glucose meter was based on the identical version of the cleared device under K073231. The sponsor has provided a letter from LifeScan supporting the sponsor's statement in Attachment I.

Discussion (Adequate): I acknowledge that RF testing on the final finished device can be performed prior to submission of the 510k application. (b)(5)

(b)(5)

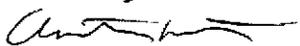
finished device. As such, I have no concerns regarding the information described in the DCAS table. Further, since Mr. Syed has reviewed the EMC testing in the DCAS table and he believes the information is adequate, I believe the table is complete.



Name
Charles Zimliki, Ph.D

4/22/08

Date



4/23/08

Review EMC – Sajjad Syed

From: Syed, Sajjad H
Sent: Wednesday, April 16, 2008 11:58 AM
To: Zimliki, Charles L* (CDRH)
Subject: K073356 Quick EMC Analysis

Hey Chip,

The sponsor claims that they are using the same RF communication protocol as the one they used to communicate with the previous BD meter. According to the sponsor, they have not changed the protocol or pump software. Plus, the new meter uses the same protocol which is why they can successfully communicate with it, without modifying their pump software. (b)(4)

(b)(4)

In my opinion, the sponsor has provided sufficient information to establish safety and effectiveness of this device.

Regards,

Sajjad

Zimliki, Charles L* (CDRH)

From: Faillace, Mark [mark.faillace@medtronic.com]
Sent: Wednesday, April 23, 2008 4:43 PM
To: Zimliki, Charles L* (CDRH)
Subject: K073356

Attachments: prescription use.pdf



prescription use.pdf
(14 KB)

Hi Chip,

Per your request, attached, please find an updated Indications for Use statement for K073356 with the Prescription Use box marked. Let me know if you need anything else.

Regards,

Mark
<<prescription use.pdf>>

[CONFIDENTIALITY AND PRIVACY NOTICE]

Information transmitted by this email is proprietary to Medtronic and is intended for use only by the individual or entity to which it is addressed, and may contain information that is private, privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient or it appears that this mail has been forwarded to you without proper authority, you are notified that any use or dissemination of this information in any manner is strictly prohibited. In such cases, please delete this mail from your records.

To view this notice in other languages you can either select the following link or manually copy and paste the link into the address bar of a web browser:
<http://emaildisclaimer.medtronic.com>

INDICATIONS FOR USE

510(k) Numbers: K030531 (MMT-512)
K031390 (MMT-712)
K040676 (MMT-515/MMT-715)

Device Names: Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps

Indications for Use: The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Prescription Use X AND/OR Over-the-Counter Use _____
(Per 21 CFR 80 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Email received – 4-21-08

From: Faillace, Mark [mark.faillace@medtronic.com]
Sent: Monday, April 21, 2008 1:58 PM
To: Zimliki, Charles L* (CDRH)
Subject: FW: K073356

Attachments: K073356 Amendment.pdf

Hi Chip,

As we discussed during our telephone conversation this morning, this message is provided to confirm that I inadvertently listed an incorrect control number for the recently cleared 510(k) for the LifeScan OneTouch UltraLink meter in the email message I sent to you last Friday. The correct number is K073231 (not K073261). An updated version of my previous message that includes correction of this error is provided below (the corrected digit of the control number appears in red).

Please accept my apologies for this error and as always, don't hesitate to let me know if you require any additional information.

Regards,

Mark Faillace
Medtronic MiniMed

—Original Message—

From: Faillace, Mark
Sent: Friday, April 18, 2008 7:56 AM
To: 'Zimliki, Charles L* (CDRH)'
Subject: RE: K073356

Hi Chip,

Yes, I can confirm that the meters used for system level RF testing, with respect to any aspects of the device that impact RF communication with compatible Medtronic MiniMed devices, were identical to the version of the meter that was cleared yesterday under K073231 and that has been manufactured for commercial distribution in the U.S. Documentation from LifeScan confirming that the meters provided to us for RF testing were equivalent to the final, finished version of the LifeScan OneTouch UltraLink meter is included in the amendment to K073356 that we submitted to FDA in early April. I've included an electronic copy of that submission with this email for your convenience. The documentation from LifeScan regarding the meters is include as Attachment 1 at the end of the document.

Thanks again for your help. Don't hesitate to let me know if you need anything else and have a great weekend.

Regards,

Mark

—Original Message—

From: Zimliki, Charles L* (CDRH) [mailto:charles.zimliki@fda.hhs.gov]
Sent: Friday, April 18, 2008 7:09 AM
To: Faillace, Mark
Subject: RE: K073356

Mark,

Thanks for the update. I have spoken with our EMC reviewer and the testing looks good. He just wanted to make sure that the testing found within your DCAS table was performed on the final finished product. This is a policy that is common across the branch. Can you confirm with Lifescan that the EMC testing you described was performed on the identical product that was cleared? If you can get this to me by Monday, I think I can get it off my desk early next week to meet your deadline as well. I'm leaving early today (3:30pm) EST, so please let me know if this is possible.
Chip

Charles "Chip" Zimlik, Ph.D.
Diabetes Team Leader / 510(k) Team Leader FDA/CDRH/ODE/DAGID/GHDB
Ph: 240-276-3671

—Original Message—

From: Faillace, Mark [mailto:mark.faillace@medtronic.com]
Sent: Thursday, April 17, 2008 5:11 PM
To: Zimlik, Charles L* (CDRH)
Subject: K073356
Importance: High

Hi Chip,

Just an update to let you know that LifeScan received the clearance for their OneTouch UltraLink glucose meter 510(k) this afternoon. I've attached a copy of the clearance letter for your convenience. I believe this was the last item you needed to complete the clearance for our 510(k) (K073356) to update the labeling for our Paradigm pumps to indicate that they can receive glucose values transmitted by the new LifeScan meter.

As I mentioned before, we'd really like to be able to begin distribution of the new LifeScan meters before the end of our fiscal year (a week from tomorrow). Sorry to ask you this, but if there's anything you can do to get the clearance letter for K073356 to us within the next few days, I'll be eternally indebted to you. Just in case there's a possibility you might be able to fax a copy of the clearance letter, my fax number is 818-576-6644.

As always, please don't hesitate to let me know if you have any questions and thanks in advance for your help.

Regards,

Mark Faillace
Medtronic MiniMed
<<K073231.pdf>>

[CONFIDENTIALITY AND PRIVACY NOTICE]

Information transmitted by this email is proprietary to Medtronic and is intended for use only by the individual or entity to which it is addressed, and may contain information that is private, privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient or it appears that this mail has been forwarded to you without proper authority, you are notified that any use or dissemination of this information in any manner is strictly prohibited. In such cases, please delete this mail from your records.

To view this notice in other languages you can either select the following link or manually copy and paste the link into the address bar of a web browser: [<<K073356 Amendment.pdf>>](http://emaildisclaimer.medtronic.com)

Email Received from Sponsor 4-17-08 file attached K073231.pdf
(Next page)

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
2095 Gaither Road
Rockville MD 20850

LifeScan, Inc.
c/o Ms. Kim Fonda
Regulatory Project Leader
1000 Gibraltar Drive
Milpitas, CA 95035

Re: k073231
Trade/Device Name: One Touch Ultralink Blood Glucose Monitoring System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: April 01, 2008
Received: April 02, 2008

Dear Ms. Fonda:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 -

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K073231

Device Name: OneTouch® UltraLink™ Blood Glucose Monitoring System

Indications For Use:

The OneTouch® UltraLink™ Blood Glucose Monitoring System is intended to be used for self-testing outside the body (*in vitro* diagnostic use) for the quantitative measurement of glucose in fresh capillary whole blood obtained from the finger, forearm or palm. The OneTouch® UltraLink™ System is intended for use by people with diabetes in a home setting and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® UltraLink™ Blood Glucose monitor may be used to transmit glucose values to appropriate MiniMed Paradigm® and Guardian® REAL Time devices using radio frequency communication.

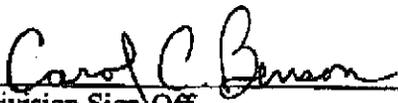
Prescription Use _____
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K 073231

- Subject Device (K073356, Attachment 2)
 - The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515, and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

- Predicate Device (K030531)
 - The Medtronic MiniMed Paradigm Model MMT-512 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
 - The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening of diabetes mellitus and is not intended for use on neonates. The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.
 - When used together, the BD Paradigm Link Glucose Monitor can automatically telemeter glucose values to the Model 512 insulin pump using radio frequency communication. The glucose value received by the Model 512 insulin pump is used as the default glucose value by the pump's bolus wizard feature if the bolus wizard is used within 12 minutes of the glucose value transmission.

- Predicate Device (K031390)
 - The Medtronic MiniMed Paradigm Model MMT-712 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

- Predicate Device (K040676)
 - The Medtronic MiniMed Paradigm Models MMT-515/MMT-715 insulin pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Discussion (Adequate- Minor changes in Indication): What to do? The sponsor clearly states on page 5 of K073356 that the intended use of their predicate devices have not changed. However, the indication of K030531 is clearly more verbose than the newly proposed indication (above). K030531 appears to contain both the indication of the pump, sensor and sensor/pump system. On December 18, 2007, I spoke with branch chief, Mr. Anthony Watson about this discrepancy and Tony requested I confer with POS (Ms. Rosecrans) to see if that particular predicate device (K030531) would qualify for a special 510(k) application given the proposed indication. Tony also asked me to look at the product labeling of the other two predicate devices having the general indication (K040676 and/or K031390). Tony felt that it might have been possible that application K030531 was the only application that specifically refers to a specific glucose meter in their product labeling. Upon inspection of K040676, I found that the product labeling (Section J, Appendix 3, Part 2) indeed specified a specific blood glucose meter (i.e., BD blood glucose meter) and yet the Agency agreed to allow a general indication to the 510(k) application. Based on this information, Tony and I believe we should allow removal of the specific glucose meter indication from the predicate device and allow the sponsor to have a general indication, which is similar to K031390 and K040676. However, Tony and I believe the sponsor should specify the glucose meter in which they have provided testing (i.e., Lifescan OneTouch Ultralink glucose meter) in their product labeling. This appears to be the precedent that has been established in K031390 and K040676. In addition, I was unable to reach Ms. Rosecrans (12-18-08), but instead, I spoke to Ms. Brandi Stuart of POS and she informed me that the removal of the glucose meter indication from K030531 could still qualify this device for a special 510(k) application since the insulin pump is not technologically different and the BD glucose meter is no longer being manufactured. Brandi believed this change (or removal) of indication is possible in the special 510(k) application realm. Because POS agreed with keeping

this issue within the special 510(k) realm, I believe the removal of the glucose meter indication from the predicate device indication is appropriate provided they detail this information in their product labeling. As the sponsor is clearly identifying communication with the LifeScan OneTouch UltraLink blood glucose meter, I have no concerns with the indication listed for the subject device.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
 - Medtronic MiniMed is submitting this special 510(k) to request clearance for minor labeling changes to Medtronic MiniMed Paradigm insulin pumps (models, MMT-512, MMT-712, & MMT-515/715). The labeling change is limited to informing the users that these devices can receive blood glucose values sent from the LifeScan OneTouch UltraLink blood glucose meter via RF telemetry. Currently, the LifeScan glucose meter is not cleared for use.
 - The sponsor states on page 5 of the application (K073356) that there are no hardware or software changes to any of the previously cleared devices associated with their optional use with the LifeScan OneTouch UltraLink glucose meter. Since the new LifeScan meter uses the same telemetry protocol as the previously cleared BD Paradigm Link Meter, all aspects of communication between the Paradigm insulin infusion pumps and the BD Paradigm Link and LifeScan OneTouch UltraLink are identical.

Discussion (Adequate): This special 510(k) application was the result of branch chief Mr. Anthony Watson and OIVD representative Ms. Patricia Bernhardt's communication with the sponsor. BD is no longer producing the glucose meter in which had communication privileges with the Paradigm insulin pumps. Through multiple conversations with Medtronic, the Agency informed Medtronic that a special 510(k) submission would be needed to modify the labeling of the infusion pumps that have 510(k) clearance (i.e., models MMT-512, -715, -515, & -715) and a PMA supplement would be needed for infusion pumps that are approved under P980022 (i.e., models MMT-522 & -722). Therefore, this special 510(k) application is in conformance with the Agency's recommendation and the modifications made to the Paradigm models (MMT-512, -715, -515, & -715) is appropriate for a special 510(k) application.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.
 - Labeling
 - The sponsor states on page 5 that labeling changes are limited to a package insert that will be included with these pumps stating they are compatible with the new LifeScan meter. A copy of this insert is provided in Attachment 1 (K073356).
 - Intended Use (K073356, Attachment 2)
 - Physical Characteristics Identical to previously cleared predicate devices.

Discussion (Additional Info Required): The sponsor is only adding the LifeScan glucose meter to their product labeling. Currently, this glucose meter is under review and is not cleared. Ms. Patricia Bernhardt of OIVD is currently the lead reviewer for this 510(k) submission (K073231) and she informed me (1-18-08) that the device will be placed on hold some time next week. Since the glucose meter is currently uncleared, the subject device cannot be cleared. This issue has been expressed clearly to Medtronic on a number of telephone conversations in which they have acknowledged this concern and this was confirmed with our advisory in deficiency #3 of K073356, so I am unsure why the sponsor would rapidly respond (application placed K073356 on hold 12-18-07, response received 12-28-07) to my additional information request when the glucose meter that they intend to communicate with does not have clearance. In discussions with branch chief Mr. Anthony Watson, he indicated that there is an Outstanding device letter that may

be appropriate, but upon reading the outstanding device boilerplate letter, it appears the sponsor has only 30 days to respond without the option of extension before the application is withdrawn/deleted. I brought this to the attention of 510k staff director, Ms. Heather Rosecrans who informed me that this outstanding device letter was intended to be used for devices that needed a clinical study and acquiring these results would take much longer than the 6 month extension the Agency gives to 510k applicants. Ms Rosecrans informed me that she thought the outstanding device letter would not be appropriate in this instance. Instead, since the application was submitted after 10-2-07, we are allowed to place the application on hold for more than 2 rounds before making a final recommendation. She recommended that we continue to place the device on hold for labeling their device with a device that is not a legally marketed device. This deficiency would be an outstanding deficiency until the glucose meter is cleared. Last, from discussions with Ms. Rosecrans, it occurred to me that the testing the sponsor has detailed in the DCAS table may not be appropriate since the sponsor is conducting testing with an uncleared glucose meter. The Agency has a long history of requiring bench testing on products that are on the final finished device. As the glucose meter is not cleared, the sponsor cannot guarantee that the testing evaluating the communication between the meter/pump has been performed on the final finished device. As such, I believe the sponsor should certify that the testing performed on the meter/subject device are on the final finished devices. I recommend deficiency #2 in K073356/S1 deficiencies.

5. A Design Control Activities Summary which includes:

A Design Control Activities Summary (DCAS) was provided by the sponsor (p. 6, K073356).

a) Risk Analysis

- Risk analysis was performed in accordance with (b)(4) (p. 3, K073356/S1).

b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied

- The sponsor provided a DCAS table in K073356/S1 (p. 2) that identifies only one risk, "pump does not display the meter reading correctly". The sponsor does say a risk analysis was performed in accordance with (b)(4) but they do not identify any risks associated with this analysis. The sponsor needs to provide this risk analysis and incorporate these risks into the DCAS table. See discussion below.

Discussion (Additional Info Required): In the original submission, the sponsor did not provide a DCAS table nor did the sponsor identify the risk analysis method used to generate their design control activity summary. The sponsor has only indicated that they have performed a system level analysis. I have been informed by Heather Rosecrans of POS that we are unable to review data/experimental reports in a special 510(k) application so I informed the sponsor that I could not evaluate the adequacy of their reports in a special 510(k) application and if they wanted to keep this as a special 510(k) application, they would need to provide a design control activity summary table in their application. The sponsor informed me on 12-17-07 that they were not aware that I could not review test reports in a special 510(k) application, but they would still like to be a special 510(k) application. Therefore, I informed the sponsor that I would be placing their application on hold and they should be receiving my concerns via email shortly. In addition to the DCAS, I also believe the sponsor should clearly show how the communication of the new LifeScan OneTouch UltraLink blood glucose meter is compatible with the Paradigm infusion pumps in their DCAS table.

In K073356/S1, the sponsor identified the risk method as being in accordance with (b)(4) thereby clarifying this issue. The sponsor also provided a DCAS table with only one risk associated with the modification, "pump displays incorrect meter readings". This is certainly a risk that needs mitigation, but the sponsor submitted EMC testing in K073356 that addresses a number of other risks (i.e, interference, immunity, etc.) that the sponsor needs to incorporate into their DCAS table. In addition, the sponsor has conducted testing on a glucose meter that is not cleared and the Agency believes testing should be performed on final finished devices. Since this testing within the DCAS table may not be appropriate because the glucose meter is not cleared, the sponsor needs to address this concern. Last, the sponsor has identified the LifeScan OneTouch Ultralink blood glucose meter in which their pumps

communicate with. However, as stated above, this glucose meter is not cleared and therefore not a legally marketed device. In a discussion with 510k staff director, Ms. Heather Rosecrans on 1-18-08, she indicated that product labeling cannot include communication privileges with devices that are not legally marketed. Since the meter is currently not a legally marketed device because it has not received clearance, the sponsor cannot claim communication privileges with this uncleared medical device. Ms. Rosecrans has indicated that this concern should be raised to the sponsor as a deficiency and since this application was submitted after 10-2-07, we can continue to ask this question until the glucose meter has been cleared. I recommend deficiency #1 & #2 in K073356/S1 deficiencies.

- c) Declaration of conformity with design controls. The declaration of conformity should include:
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
 - Found in K073356, Attachment 3
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
 - Found in K073356, Attachment 3

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

- Truthful and Accuracy Statement – K073356, Attachment 5
- 510(k) Statement – K073356, Attachment 4
- Indication for Use page – K073356, Attachment 2

Contact History

12-17-07 I informed sponsor that we cannot review test data in a special 510(k) and asked the sponsor if they would like to convert the special to a traditional 510(k) application. The sponsor informed me that they believe they would like to keep the application as a special 510(k). I informed them that we could not review the test data in a special 510(k) application and that I would be placing this application on hold and requesting additional information with regards to a proper Design Control Activity Summary Table. Sponsor agreed to be being placed on hold and is awaiting an email with the Agency's concerns.

1-29-08 Emailed sponsor a list of concerns regarding their DCAS table and informed the sponsor that their device is on hold. Email attached.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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:
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:
Sponsor did not provide an adequately detailed DCAS table associated with the modifications made to the product labeling.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
Sponsor should identify all risks associated with their device modification and detail these risk in their DCAS table.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

K073356 Deficiencies

The sponsor must provide additional information for me to determine if the subject device is substantially equivalent to the predicate devices.

1. The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns.
 - a. Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g., EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Control Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.

Sponsor's Response

As indicated in our original submission, there are no hardware or software changes to Paradigm insulin infusion pumps related to their use with the new LifeScan OneTouch UltraLink glucose meter since the new LifeScan meter was developed using the same RF telemetry specification used in the previously cleared BD Paradigm Link meter. Since there were no hardware or software changes to any Medtronic MiniMed devices, design control activities focused on confirmatory system level testing conducted using Paradigm insulin infusion pumps in combination with LifeScan OneTouch UltraLink meters. These verification activities are summarized in the table (p. 2, K073356/S1).

***Discussion (Additional Info Required):** The sponsor has provided a DCAS table on page 2 of K073356/S1. However, the sponsor provided a general summary of the testing they performed on the device system. I only know this because in the original submission of K073356, the sponsor provided testing in which the Agency informed them we could not review unless they wanted to convert their application from a special to a traditional 510k application. Since the sponsor did not want to convert the submission to a traditional, the sponsor is required to provide a DCAS table that identifies the risks associated with communicating with a new glucose meter. The sponsor is correct in that there are no design changes to the pump, but since the sponsor is claiming that the pump is communicating with another medical device (i.e., LifeScan OneTouch Ultralink), the system does have other risks associated with the system (e.g., risk of interference, immunity, or the pump displays incorrect meter information, etc.). These risks should be documented in the DCAS table. The sponsor appears to only have provided a very generalized description and does not clearly identify the risks associated with adding a new glucose meter device to the system. Clearly there are risks associated with adding a meter to the system or the sponsor would not have submitted bench testing data in their original application. In addition, the sponsor has stated in their risk analysis that they have identified the risks in accordance to (b)(4). The risks associated with this standard should be incorporated into their DCAS table. Also, the sponsor has clearly identified verification activities by confirming that "appropriate" communication occurs between the pump and the new meter, but the sponsor does not identify what they believe is appropriate communication. It is apparent that appropriate communication is important since the meter reading can be used for insulin dose adjustments. Last, the acceptance criteria only specified that the glucose meter can communicate with the pump in eight different directions as the only acceptance criteria, but the sponsor did not specify any type of acceptance criteria with respect to interference, immunity, etc. I believe the generalized DCAS table provided by the sponsor is grossly inadequate in that it does not identify the risks associated with adding a new glucose meter device to communicate with the pump. I recommend deficiency #1 in K073356/S1 deficiencies.*

- b. In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.

Sponsor's Response

The RF protocol used in the BD Paradigm Link and the LifeScan OneTouch UltraLink glucose meters is described in the software requirements specification (ES9411) provided in Attachment 1. This specification was provided to LifeScan by Medtronic MiniMed prior to their development of the OneTouch UltraLink glucose meter and served as the basis for LifeScan's development of the new meter's RF hardware and software. The successful completion of the system level communications testing confirmed that the new LifeScan meter successfully implements this telemetry protocol. Additional details regarding verification testing performed by LifeScan to confirm that the OneTouch UltraLink meter complies with all specified requirements are provided in the 510(k) submitted by LifeScan K073231 for the OneTouch UltraLink meter.

Discussion (Adequate): The sponsor has provided the communication specifications of the pump and believes their system level testing proves the meter and pump communicate properly. I believe that if the sponsor adequately describes all the system level testing that the sponsor has performed that this is sufficient data. Since I have asked for a detailed DCAS table above, I believe this concern will be addressed with such a DCAS table. I have no additional concerns.

- c. As part of your DCAS table, please identify what risk analysis (e.g., FMEA) was used to analyze the risk associated with your device/labeling modification.

Sponsor's Response

The analysis of risks associated with our labeling modification to indicate compatibility with the LifeScan OneTouch UltraLink meter was conducted in accordance with (b)(4). This analysis is documented in an engineering report and is provided as Attachment 2 of this submission for your reference.

Discussion (Adequate): The sponsor has provided a risk analysis that should be incorporated into their DCAS table. I am unsure why they did not incorporate this information into the table. As I have already asked for a detailed DCAS table, I believe the risks associated in Attachment 2 will be included in the DCAS table. Since the sponsor said their risk analysis is in accordance with (b)(4) (b)(4) the sponsor has identified the risk analysis method for their device. As such, I have no additional concerns.

2. You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e., LifeScan OneTouch Ultralink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.

Sponsor's Response

We currently only intend to label our insulin pumps to indicate they are capable of receiving glucose values transmitted by the BD Paradigm Link meter and the new LifeScan OneTouch UltraLink meter. The statement in our original submission indicating that "Glucose values from any FDA cleared home glucose meter may be used as input for the pump's "Bolus Wizard" and therefore there is no limitation on pump functionality even when used with meters other than the BD Paradigm Link or LifeScan OneTouch UltraLink" is referring to the fact that a glucose value calculator. However, at this time, there are no other meters that will be marketed in the United States that will included the ability to transmit glucose values via RF to Paradigm infusion pumps.

Discussion (Adequate): The sponsor has clearly stated that the only two meters for which their pump can receive glucose meter readings are from the BD Paradigm Link or the LifeScan OneTouch UltraLink glucose meter. The sponsor has specifically identified the only two meters for which this pump can be used. Therefore, I believe the sponsor has provided adequate information.

3. You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch Ultralink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that your application containing your labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.

Sponsor's Response

We understand and acknowledge that our special 510(k) can not be cleared until FDA has cleared the LifeScan 510(k) for the OneTouch UltraLink glucose meter.

Discussion (Additional Info Required): The sponsor has acknowledged that the subject device cannot be cleared prior to the clearance of the LifeScan OneTouch Ultralink blood glucose meter. I have discussed the LifeScan OneTouch Ultralink blood glucose meter review (K073231) with the OIVD lead reviewer, Ms. Patricia Bernhardt on Friday 1-18-08 and she informed me that K073231 is still under review and the application will be put on hold for additional information. Since the glucose meter is currently uncleared, the subject device cannot be cleared. This issue has been expressed clearly to Medtronic on a number of telephone conversations in which they have acknowledged this concern and was confirmed with our advisory above, so I am unsure why the sponsor would rapidly respond (application placed K073356 on hold 12-18-07, response received 12-28-07) to my additional information request when the glucose meter that they intend to communicate with does not have clearance. In discussions with branch chief Mr. Anthony Watson, he indicated that there is an Outstanding device letter that may be appropriate, but upon reading the outstanding device boilerplate letter, it appears the sponsor has only 30 days to respond without the option of extension before the application is withdrawn/deleted. I brought this to the attention of 510k staff director, Ms. Heather Rosecrans who informed me that this outstanding device letter was intended to be used for devices that needed a clinical study and the results of this study would take much longer than the 6 month extension the Agency gives to 510k applicants. Ms Rosecrans informed me that she thought the outstanding device letter would not be appropriate in this instance. Instead, since the application was submitted after 10-2-07, we are allowed to place the application on hold for more than 2 rounds before making a final recommendation. She recommended that we continue to place the device on hold for labeling their device with a device that is not a legally marketed device. This deficiency would be an outstanding deficiency until the glucose meter is cleared. Last, from discussions with Ms. Rosecrans, it occurred to me that the testing the sponsor has detailed in the DCAS table may not be appropriate since the sponsor is conducting testing with an uncleared glucose meter. The Agency has a long history of requiring bench testing on products that are on the final finished device. As the glucose meter is not cleared, the sponsor cannot guarantee that the testing evaluating the communication between the meter/pump has been performed on the final finished device. As such, I believe the sponsor should certify that the testing performed on the meter/subject device are both on the final finished device. I recommend deficiency #2 in K073356/S1 deficiencies.

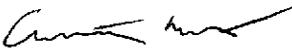
K073356/S1 Deficiencies

1. You have provided a Design Control Activities Summary (DCAS) table that identifies only one risk with your device and the LifeScan OneTouch UltraLink glucose meter (i.e., pump displaying different glucose value than the glucose meter). However, the Agency believes there are additional risks that you have not incorporated into your DCAS table that should be included. For example, the Agency believes there are Electromagnetic Compatibility (EMC) concerns that your device may not communicate properly with the LifeScan OneTouch UltraLink glucose meter. Presumably, you have tested the communication of your pump with the LifeScan OneTouch UltraLink glucose meter for example interference or immunity using a variety of phones, metal detectors, household emitters, etc. that mitigates such EMC concerns. This type of testing must be incorporated into your DCAS table with each test having their own specific risk and acceptance criteria that allows you to mitigate the identified risk. In addition, you have stated that you have performed a formal risk analysis according to (b)(4) please incorporate those risks and their corresponding verification activity, acceptance criteria, and results of verification into your DCAS table that allows you to claim communication compatibility of your pump with the LifeScan OneTouch UltraLink glucose meter.
2. You have indicated that the Paradigm pump models MMT-512, -712, -515, and -715 are to communicate with the LifeScan OneTouch Ultralink blood glucose meter. However, the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter as being a legally marketed device. Please address the following concerns.
 - a. The Agency believes your device product labeling can only identify communication with medical devices that have been Agency cleared. Please provide the 510(k) numbers of all medical devices with which your pump models are labeled to communicate with.
 - b. You have provided a DCAS table that identifies testing of your pump with the LifeScan OneTouch Ultralink blood glucose meter. The Agency believes testing of your device with other medical devices should be performed on final finished devices for every device. Since the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter being a legally marketed device, bench testing with this device cannot be performed on the final finished device. Please update your DCAS table to include testing of your device with only legally marketed (i.e., final finished device) blood glucose

meters that you intend to communicate with (i.e., LifeScan OneTouch Ultralink blood glucose meter).
Please certify that all testing described in the DCAS table are on final finished devices.


Name _____ Date 1/29/08
Charles Zimlki, Ph.D

CZ 1/29/08

 1/30/08

Email Sent to Sponsor 1-29-08

From: Zimliki, Charles L* (CDRH)
Sent: Tuesday, January 29, 2008 4:28 PM
To: 'Faillace, Mark'
Cc: Watson, Anthony
Subject: K073356/S1 - On Hold

Mark,

Good evening. The Agency still has concerns with regards to your pump application and I will be placing your 510(k) application, K073356/S1 on hold until you can address the following concerns that I have attached below. Please be advised that this document is officially on hold and all responses to the listed concerns must be sent as a supplement to application K073356 to the document mail center. I believe it would be helpful to discuss these concerns before responding. Please feel free to contact me at 240-276-3671. Also, please acknowledge receipt of this email by sending me a quick acknowledgement email.

Sincerely,
 Chip

K073356/S1 Deficiencies

1. You have provided a Design Control Activities Summary (DCAS) table that identifies only one risk with your device and the LifeScan OneTouch UltraLink glucose meter (i.e., pump displaying different glucose value than the glucose meter). However, the Agency believes there are additional risks that you have not incorporated into your DCAS table that should be included. For example, the Agency believes there are Electromagnetic Compatibility (EMC) concerns that your device may not communicate properly with the LifeScan OneTouch UltraLink glucose meter. Presumably, you have tested the communication of your pump with the LifeScan OneTouch UltraLink glucose meter for example interference or immunity using a variety of phones, metal detectors, household emitters, etc. that mitigates such EMC concerns. This type of testing must be incorporated into your DCAS table with each test having their own specific risk and acceptance criteria that allows you to mitigate the identified risk. In addition, you have stated that you have performed a formal risk analysis according to (b)(4) please incorporate those risks and their corresponding verification activity, acceptance criteria, and results of verification into your DCAS table that allows you to claim communication compatibility of your pump with the LifeScan OneTouch UltraLink glucose meter.
2. You have indicated that the Paradigm pump models MMT-512, -712, -515, and -715 are to communicate with the LifeScan OneTouch Ultralink blood glucose meter. However, the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter as being a legally marketed device. Please address the following concerns.
 - a. The Agency believes your device product labeling can only identify communication with medical devices that have been Agency cleared. Please provide the 510(k) numbers of all medical devices with which your pump models are labeled to communicate with.
 - b. You have provided a DCAS table that identifies testing of your pump with the LifeScan OneTouch Ultralink blood glucose meter. The Agency believes testing of your device with other medical devices should be performed on final finished devices for every device. Since the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter being a legally marketed device, bench testing with this device cannot be performed on the final finished device. Please update your DCAS table to include testing of your device with only legally marketed (i.e., final finished device) blood glucose meters that you intend to communicate with (i.e., LifeScan OneTouch Ultralink blood glucose meter). Please certify that all testing described in the DCAS table are on final finished devices.

Charles "Chip" Zimliki, Ph.D.
 Diabetes Team Leader
 FDA/CDRH/ODE/DAGID/GHDB
 Ph: 240-276-3671

Email Received from Sponsor 1-25-08

From: Faillace, Mark [mark.faillace@medtronic.com]

Sent: Friday, January 25, 2008 11:19 AM

To: Zimlik, Charles L* (CDRH)

Subject: Amendment To K073356

Attachments: Amendment To K073356.pdf

Hi Chip,

In reviewing our recent amendment to K073356, I noticed that one line of text did not print at the top of page 4 of our submission and therefore our response to the next to last question was not complete in the hardcopy submitted to the Document Mail Center. I'm not sure how that happened (since the line of text appears in the Word document) but to eliminate the possibility of any confusion, I've attached a PDF version of the response that includes the missing text.

Sorry I didn't catch this before. As always, don't hesitate to let me know if you require any additional information.

Regards,

Mark Faillace

Medtronic MiniMed

<<Amendment To K073356.pdf>>

CONFIDENTIALITY AND PRIVACY NOTICE

Information transmitted by this email is proprietary to Medtronic and is intended for use only by the individual or entity to which it is addressed, and may contain information that is private, privileged, confidential or exempt from disclosure under applicable law. If you are not the intended recipient or it appears that this mail has been forwarded to you without proper authority, you are notified that any use or dissemination of this information in any manner is strictly prohibited. In such cases, please delete this mail from your records.

To view this notice in other languages you can either select the following link or manually copy and paste the link into the address bar of a web browser: <http://emaildisclaimer.medtronic.com>

Email Received from Sponsor 1-25-08 file attached K073356(2).pdf

December 28, 2007

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

**RE: Supplement to K073356: Submission of Additional Information Requested By
Reviewer Dr. Charles Zimliki In Email Message Dated December 18, 2007**

Dear Sir or Madam:

Medtronic MiniMed is submitting this supplement to premarket notification K073356 to provide the additional information requested by reviewer Charles Zimliki in an email dated December 18, 2007. For your convenience, each request included in Dr. Zimliki's message are repeated, *verbatim* below and followed by our response.

1. The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns:

a. Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and result of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g. EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.

Medtronic MiniMed Response

As indicated in our original submission, there are no hardware or software changes to Paradigm insulin infusion pumps related to their use with the new LifeScan OneTouch UltraLink glucose meter since the new LifeScan meter was developed using the same RF telemetry specification used in the previously cleared BD Paradigm Link meter. Since there were no hardware or software changes to any Medtronic MiniMed devices, design control activities focused on confirmatory system level testing conducted using Paradigm insulin infusion pumps in combination with LifeScan OneTouch UltraLink meters. These verification activities are summarized in the table that follows:

Design Control Activities Summary

Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Modification of pump labeling to indicate that these pumps can receive glucose values transmitted by the LifeScan OneTouch UltraLink glucose meter (in addition to the current BD Paradigm Link glucose meter)			(b)(4)	

b. *In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.*

Medtronic MiniMed Response

The RF protocol used in the BD Paradigm Link and the LifeScan OneTouch UltraLink glucose meters is described in the software requirements specification (ES9411) provided as Attachment 1. This specification was provided to LifeScan by Medtronic MiniMed prior to their development of the OneTouch UltraLink glucose meter and served as the basis for LifeScan's development of the new meter's RF hardware and software. The successful completion of the system level communications testing confirmed that the new LifeScan meter successfully implements this telemetry protocol. Additional details regarding verification testing performed by LifeScan to confirm that the OneTouch UltraLink meter complies with all specified requirements are provided in the 510(k) submitted by LifeScan (K073231) for the OneTouch UltraLink meter.

c. *As part of your DCAS table, please identify what risk analysis (e.g. FMEA) was used to analyze the risks associated with your device/labeling modification.*

Medtronic MiniMed Response

The analysis of risks associated with our labeling modification to indicate compatibility with the LifeScan OneTouch UltraLink meter was conducted in accordance with (b)(4). This analysis is documented in an engineering report (ER07-4896) and is provided as Attachment 2 of this submission for your reference.

2. *You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e LifeScan OneTouch UltraLink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.*

Medtronic MiniMed Response

We currently only intend to label our insulin pumps to indicate they are capable of receiving glucose values transmitted by the BD Paradigm Link meter and the new LifeScan OneTouch UltraLink meter. The statement in our original submission indicating that "Glucose values from any FDA cleared home glucose meter may be used as input for the pump's "Bolus Wizard" and therefore there is no limitation on pump functionality even when used with meters other than the BD Paradigm Link or LifeScan OneTouch UltraLink." is referring to the fact that a glucose value

from any glucose meter can be manually entered by the user for use in the "Bolus Wizard" calculator. However, at this time, there are no other meters that will be marketed in the United States that will include the ability to transmit glucose values via RF to Paradigm infusion pumps.

3. *You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch UltraLink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that you application containing labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.*

Medtronic MiniMed Response

We understand and acknowledge that our special 510(k) can not be cleared until FDA has cleared the LifeScan 510(k) for the OneTouch UltraLink glucose meter.

Please do not hesitate to contact me via telephone (818-576-5616) or email (mark.faillace@medtronic.com) if you require any additional information or clarification.

Sincerely,

Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting

Attachment 1
Telemetry Specification

Attachment 2

Risk Analysis



COVER SHEET MEMORANDUM

From: Reviewer Name Charles Zanklik
Subject: 510(k) Number K073356
To: The Record TH

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 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://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB_REVIATED_STANDARDS_DATA_FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/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)?			
Does this device include an Animal Tissue Source?			
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: [Signature] GADW GHPB 12/18/07
(Branch Chief) (Branch Code) (Date)

Final Review: _____
(Division Director) (Date)

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):	YES	NO
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see <u>H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC</u>)		
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		
3. Does this device type require a PMA by regulation? (Please see management.)		
Questions 4-8 are intended to help you start your review:	YES	NO
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)		
5. a. Did the firm request expedited review? (See management,) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		

- Subject Device (K073356, Attachment 2)
 - The Medtronic MiniMed Paradigm Model MMT-512, MMT-712, MMT-515, and MMT-715 insulin infusion pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

- Predicate Device (K030531)
 - The Medtronic MiniMed Paradigm Model MMT-512 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.
 - The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening of diabetes mellitus and is not intended for use on neonates. The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.
 - When used together, the BD Paradigm Link Glucose Monitor can automatically telemeter glucose values to the Model 512 insulin pump using radio frequency communication. The glucose value received by the Model 512 insulin pump is used as the default glucose value by the pump's bolus wizard feature if the bolus wizard is used within 12 minutes of the glucose value transmission.

- Predicate Device (K031390)
 - The Medtronic MiniMed Paradigm Model MMT-712 insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

- Predicate Device (K040676)
 - The Medtronic MiniMed Paradigm Models MMT-515/MMT-715 insulin pumps are indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Discussion (Additional Info Required): *What to do? The sponsor clearly states on page 5 of the application that the intended use of their predicate devices have not changed. However, the indication of K030531 is clearly more verbose than the newly proposed indication (above). K030531 appears to contain both the indication of the pump, sensor and sensor/pump system. On December 18, 2007, I spoke with branch chief, Mr. Anthony Watson about this discrepancy and Tony requested I confer with POS (Ms. Rosecrans) to see if that particular predicate device (K030531) would qualify for a special 510(k) application given the proposed indication. Tony also asked me to look at the product labeling of the predicate device having the general indication (K040676 and/or K031390). Tony felt that it might have been possible that application K030531 was the only application that specifically refers to a specific glucose meter. Upon inspection of K040676, I found that the product labeling (Section J, Appendix 3, Part 2) indeed specified a specific blood glucose meter (i.e., BD blood glucose meter) and yet the Agency agreed to allow a general indication to the 510(k) application. Based on this information, Tony and I believe we should allow removal of the glucose meter indication from the predicate device and allow the sponsor to have a general indication, which is similar to K031390 and K040676. However, I believe the sponsor should specify the glucose meter in which they have provided testing (i.e., Lifescan OneTouch Ultralink glucose meter) in their product labeling. This appears to be the precedent that has been established in K031390 and K040676. Please see deficiency #2. To further support the ability to keep this a special 510(k) application, later that day (12-18-07), I tried to reach Ms. Rosecrans, but she was unavailable for most of the day with meetings. Instead, I spoke to Ms. Brandi Stuart of POS and she informed me that the removal of the glucose meter indication from K030531 could still qualify this device for a special 510(k) application since the insulin pump is not technologically different and the BD glucose meter is no longer being manufactured. Brandi believed this change (or removal) of indication is*

possible in the special 510(k) application realm. Because POS agreed with keeping this issue within the special 510(k) realm.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
 - Medtronic MiniMed is submitting this special 510(k) to request clearance for minor labeling changes to Medtronic MiniMed Paradigm insulin pumps (models, MMT-512, MMT-712, & MMT-515/715). The labeling change is limited to informing the users that these devices can receive blood glucose values sent from the LifeScan OneTouch UltraLink blood glucose meter via RF telemetry. Currently, the LifeScan glucose meter is not cleared for use.
 - The sponsor states on page 5 of the application that there are no hardware or software changes to any of the previously cleared devices associated with their optional use with the LifeScan OneTouch UltraLink glucose meter. Since the new LifeScan meter uses the same telemetry protocol as the previously cleared BD Paradigm Link Meter, all aspects of communication between the Paradigm insulin infusion pumps and the BD Paradigm Link and LifeScan OneTouch UltraLink are identical.

Discussion (Adequate): This special 510(k) application was the result of branch chief Mr. Anthony Watson and OIVD representative Ms. Patricia Bernhardt's communication with the sponsor. BD is no longer producing the glucose meter in which had communication privileges with the Paradigm insulin pumps. Through multiple conversations with Medtronic, the Agency informed Medtronic that a special 510(k) submission would be needed to modify the labeling of the infusion pumps that have 510(k) clearance (i.e., models MMT-512, -715, -515, & -715) and a PMA supplement would be needed for infusion pumps that are approved under P980022 (i.e., models MMT-522 & -722). Therefore, this special 510(k) application is in conformance with the Agency's recommendation and the modifications made to the Paradigm models (MMT-512, -715, -515, & -715) is appropriate for a special 510(k) application.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, etc.
 - Labeling
 - The sponsor states on page 5 that labeling changes are limited to a package insert that will be included with these pumps stating they are compatible with the new LifeScan meter. A copy of this insert is provided in Attachment 1.
 - Intended Use (K073356, Attachment 2)
 - Physical Characteristics Identical to previously cleared predicate devices.

Discussion (Advisory): The sponsor is only adding the LifeScan glucose meter to their product labeling. Currently, this glucose meter is under review and is not cleared. Ms. Patricia Bernhardt of OIVD is currently reviewing this 510(k) submission (K073231) and she has informed me that the device application will be under review until January 14, 2008. Due to the fact that the due date for this application is before the decision of OIVD and I have additional concerns with respect to the DCAS table (below), I believe I should add an advisory to my additional information request. I recommend deficiency #2 (Advisory #1).

5. A **Design Control Activities Summary** which includes:

A Design Control Activities Summary (DCAS) was provided by the sponsor (p. 6, K073356).

- a) Risk Analysis

- Risk analysis was not specified by the sponsor. The sponsor needs to provide this information. See discussion below.
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
- The sponsor did not provide a DCAS table that identifies the risks and/or procedures to verify the compatibility of this meter with respect to all of the Paradigm insulin pumps. The sponsor needs to provide this risk analysis and table. See discussion below.

***Discussion (Additional Info Required):** The sponsor did not provide a DCAS table nor did the sponsor identify the risk analysis method used to generate their design control activity summary. The sponsor has only indicated that they have performed a system level analysis. I have been informed by Heather Rosecrans of POS that we are unable to review data/experimental reports in a special 510(k) application so I informed the sponsor that I could not evaluate the adequacy of their reports in a special 510(k) application and if they wanted to keep this as a special 510(k) application, they would need to provide a design control activity summary table in their application. The sponsor informed me on 12-17-07 that they were not aware that I could not review test reports in a special 510(k) application, but they would still like to be a special 510(k) application. Therefore, I informed the sponsor that I would be placing their application on hold and they should be receiving my concerns via email shortly. In addition to the DCAS, I also believe the sponsor should clearly show how the communication of the new LifeScan OneTouch UltraLink blood glucose meter is compatible with the Paradigm infusion pumps in their DCAS table. I recommend deficiency #1 to the sponsor.*

- c) Declaration of conformity with design controls. The declaration of conformity should include:
- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.
 - Found in K073356, Attachment 3
 - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
 - Found in K073356, Attachment 3

6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).

- Truthful and Accuracy Statement – K073356, Attachment 5
- 510(k) Statement – K073356, Attachment 4
- Indication for Use page – K073356, Attachment 2

Contact History

12-18-07 I informed sponsor that we cannot review test data in a special 510(k) and asked the sponsor if they would like to convert the special to a traditional 510(k) application. The sponsor informed me that they believe they would like to keep the application as a special 510(k). I informed them that we could not review the test data in a special 510(k) application and that I would be placing this application on hold and requesting additional information with regards to a proper Design Control Activity Summary Table. Sponsor agreed to be being placed on hold and is awaiting an email with the Agency's concerns.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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://erom.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:
Sponsor did not provide a DCAS table associated with the modifications made to the product labeling.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
Sponsor should provide a DCAS table.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

K073356 Deficiencies

The sponsor must provide additional information for me to determine if the subject device is substantially equivalent to the predicate devices.

1. The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns.
 - a. Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g., EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Control Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.
 - b. In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.
 - c. As part of your DCAS table, please identify what risk analysis (e.g., FMEA) was used to analyze the risk associated with your device/labeling modification.

2. You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e., LifeScan OneTouch Ultralink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.

3. You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch Ultralink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that your application containing your labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.



Name
Charles Zimliki, Ph.D

12/18/07

Date

CFE Note: Tony Watson reviewed the deficiencies on 12/18/07 prior to assigning branch chief responsibilities to me.


For ADW

12/18/07

Email Sent to Sponsor 12-18-07

From: Zimliki, Charles L* (CDRH)
Sent: Tuesday, December 18, 2007 6:08 PM
To: 'Faillace, Mark'
Cc: Watson, Anthony
Subject: K073356 - On Hold - Additional Information needed
Attachments: Generic DESIGN CONTROL ACTIVITIES SUMMARY TABLES.DOC
 Mr. Faillace,

My name is Chip Zimliki and I am the reviewer for your special 510(k) application, K073356, the Paradigm Insulin pump (models MMT-512, -712, -515, & -715). I have some questions that need addressed and I will be placing your device application on hold until you can address the following concerns that I have attached below. Please be advised that this document is officially on hold and all responses to the listed concerns must be sent as a supplement to application K073356 to the document mail center. Please feel free to contact me at 240-276-3671 if you have any questions. Also, please acknowledge receipt of this email, by sending me a quick acknowledgement/email.

Sincerely,

Chip

Charles "Chip" Zimliki, Ph.D.
 Diabetes Team Leader
 FDA/CDRH/ODE/DAGID/GHDB
 Ph: 240-276-3671

K073356 Deficiencies

1. The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns.
 - a. Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and results of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g., EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Control Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.
 - b. In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.
 - c. As part of your DCAS table, please identify what risk analysis (e.g., FMEA) was used to analyze the risk associated with your device/labeling modification.
2. You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e., LifeScan OneTouch UltraLink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.
3. You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch Ultralink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that your application containing your labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.



Generic DESIGN
 CONTROL ACTIVIT..

Generic “Design Control Activities Summary”

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Sponsor should identify each difference between the modified device and the predicate (cleared) device	(b)(4)			

Sample “Design Control Activities Summary”

Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Modification of Component “A” by decreasing (b)(4)	(b)(4)			

January 02, 2008

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

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Product: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515

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



K073356/S'

Medtronic Diabetes
18000 Devonshire Street
Northridge CA 91325 1219
800-minimed
www.minimed.com

December 28, 2007

FDA CDRH DMC

DEC 31 2007

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

Received

RE: Supplement to K073356: Submission of Additional Information Requested By Reviewer Dr. Charles Zimlik In Email Message Dated December 18, 2007

Dear Sir or Madam:

Medtronic MiniMed is submitting this supplement to premarket notification K073356 to provide the additional information requested by reviewer Charles Zimlik in an email dated December 18, 2007. For your convenience, each request included in Dr. Zimlik's message are repeated, *verbatim* below and followed by our response.

1. *The Design Control Activities Summary provided on page 6 of your application needs modification. Please address the following concerns:*

a. *Your Special 510(k) does not include a Design Control Activities Summary (DCAS) table. An adequate Design Control Activities Summary table is an essential part of a Special 510(k) submission. Therefore, please provide a DCAS table, which identifies specific information on the device modifications, all risks which result from these changes, verification activities, and specific (quantitative) acceptance criteria, and result of verification. To elaborate, the DCAS table should address potential risks due to the addition of adding the LifeScan OneTouch UltraLink blood glucose meter to the communication privileges of your paradigm insulin pump models (e.g. EMC testing, communication compatibility testing, interference/immunity testing, etc.). Any relevant changes in the manufacturing process, including the sterilization method, should be considered as well. We have attached a copy of a Generic Design Activity Summary Table that addresses our concerns. Please modify your Design Control Activities Summary to include this information.*

K11

67

Medtronic MiniMed Response

As indicated in our original submission, there are no hardware or software changes to Paradigm insulin infusion pumps related to their use with the new LifeScan OneTouch UltraLink glucose meter since the new LifeScan meter was developed using the same RF telemetry specification used in the previously cleared BD Paradigm Link meter. Since there were no hardware or software changes to any Medtronic MiniMed devices, design control activities focused on confirmatory system level testing conducted using Paradigm insulin infusion pumps in combination with LifeScan OneTouch UltraLink meters. These verification activities are summarized in the table that follows:

Design Control Activities Summary

Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Modification of pump labeling to indicate that these pumps can receive glucose values transmitted by the LifeScan OneTouch UltraLink glucose meter (in addition to the current BD Paradigm Link glucose meter)				

Risk Interference Immunity details

b. *In addition to the requested information in 1a, you have also identified in your application that the LifeScan OneTouch UltraLink blood glucose meter uses identical communication as the BD Paradigm Link glucose meter. Please specify the communication characteristics of each glucose meter and your paradigm insulin pumps that allow you to make this claim. Please include this information in your DCAS table.*

Medtronic MiniMed Response

The RF protocol used in the BD Paradigm Link and the LifeScan OneTouch UltraLink glucose meters is described in the software requirements specification (ES9411) provided as Attachment 1. This specification was provided to LifeScan by Medtronic MiniMed prior to their development of the OneTouch UltraLink glucose meter and served as the basis for LifeScan's development of the new meter's RF hardware and software. The successful completion of the system level communications testing confirmed that the new LifeScan meter successfully implements this telemetry protocol. Additional details regarding verification testing performed by LifeScan to confirm that the OneTouch UltraLink meter complies with all specified requirements are provided in the 510(k) submitted by LifeScan (K073231) for the OneTouch UltraLink meter.

c. *As part of your DCAS table, please identify what risk analysis (e.g. FMEA) was used to analyze the risks associated with your device/labeling modification.*

Medtronic MiniMed Response

The analysis of risks associated with our labeling modification to indicate compatibility with the LifeScan OneTouch UltraLink meter was conducted in accordance with (b)(4). This analysis is documented in an engineering report (ER07-4896) and is provided as Attachment 2 of this submission for your reference.

2. *You have indicated that your device can be used with any glucose meter having similar communication protocols, but you have not provided testing to support the safe use of your device with all glucose meters. The Agency believes, the testing reflected in your DCAS table should support the safe use of your device for every glucose meter in which you intend to label your device with (i.e LifeScan OneTouch UltraLink blood glucose meter) and your labeling should stipulate testing has only been performed on the glucose meters you identify.*

Medtronic MiniMed Response

We currently only intend to label our insulin pumps to indicate they are capable of receiving glucose values transmitted by the BD Paradigm Link meter and the new LifeScan OneTouch UltraLink meter. The statement in our original submission indicating that "Glucose values from any FDA cleared home glucose meter may be used as input for the pump's "Bolus Wizard" and therefore there is no limitation on pump functionality even when used with meters other than the BD Paradigm Link or LifeScan OneTouch UltraLink." is referring to the fact that a glucose value

calculator. However, at this time, there are no other meters that will be marketed in the United States that will include the ability to transmit glucose values via RF to Paradigm infusion pumps.

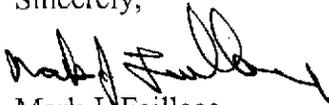
3. *You have submitted this special 510(k) application for your Paradigm insulin pump models MMT-512, MMT-712, MMT-515, and MMT-715 because of a labeling change in which you indicate compatibility with the LifeScan OneTouch UltraLink blood glucose meter. However, currently this meter does not have Agency clearance. Please be advised that your application containing labeling changes cannot receive clearance until LifeScan receives clearance from the Agency for their glucose meter.*

Medtronic MiniMed Response

We understand and acknowledge that our special 510(k) can not be cleared until FDA has cleared the LifeScan 510(k) for the OncTouch UltraLink glucose meter.

Please do not hesitate to contact me via telephone (818-576-5616) or email (mark.faillace@medtronic.com) if you require any additional information or clarification.

Sincerely,



Mark J. Faillace

Senior Director, Regulatory Affairs and Product Reporting

Attachment 1
Telemetry Specification



Medtronic
MINIMED

Doc Type: **Z20** Doc Prefix: **ES** Doc Number: **9411** Color:

Category: **SOFTWARE REQUIREMENTS SPEC**

(b)(4)

Pages 217 through 222 redacted for the following reasons:

Exemption 4

Attachment 2

Risk Analysis



Medtronic

MINIMED

Doc Type: **Z25** Doc Prefix: **ER** Doc Number: **07-4896** Color:

Category: **RISK ANALYSIS**

Doc Description: **Lifescan Meter Final Risk Analysis**

(b)(4)

Pages 225 through 233 redacted for the following reasons:

Exemption 4: Proprietary Test Data

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

April 03, 2008

MEDTRONIC MINIMED
18000 DEVONSHIRE ST.
NORTHRIDGE, CA 91325
ATTN: MARK J. FAILLACE

510(k) Number: K073356
Product: PARADIGM INSULIN
INFUSION PUMP,
MODELS MMT-512,
MMT-712, MMT-515

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



K073356/82

Medtronic Diabetes
18000 Devonshire Street
Northridge CA 91325-1219
800-minimed
www.minimed.com

Received
APR - 2 2008
FDA CDRH DMC

April 1, 2008

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

RE: Amendment to K073356: Submission of Additional Information Requested By Reviewer Dr. Charles Zimliki In Email Message Dated January 29, 2008

Dear Sir or Madam:

Medtronic MiniMed is submitting this amendment to premarket notification K073356 to provide the additional information requested by reviewer Charles Zimliki in an email dated January 29, 2008. For your convenience, each request included in Dr. Zimliki's message is repeated, *verbatim* in italics below and followed by our response.

1. You have provided a Design Control Activities Summary (DCAS) table that identifies only one risk with your device and the LifeScan OneTouch UltraLink glucose meter (i.e., pump displaying different glucose value than the glucose meter). However, the Agency believes there are additional risks that you have not incorporated into your DCAS table that should be included. For example, the Agency believes there are Electromagnetic Compatibility (EMC) concerns that your device may not communicate properly with the LifeScan OneTouch UltraLink glucose meter. Presumably, you have tested the communication of your pump with the LifeScan OneTouch UltraLink glucose meter for example interference or immunity using a variety of phones, metal detectors, household emitters, etc. that mitigates such EMC concerns. This type of testing must be incorporated into your DCAS table with each test having their own specific risk and acceptance criteria that allows you to mitigate the identified risk. In addition, you have stated that you have performed a formal risk analysis according to (b)(4) please incorporate those risks and their corresponding verification activity, acceptance criteria, and results of verification into your DCAS table that allows you to claim communication compatibility of your pump with the LifeScan OneTouch UltraLink glucose meter.

K30

Medtronic MiniMed Response

As indicated in our initial 510(k) submission, the capability for Paradigm insulin infusion pumps (MMT-512, MMT-712, MMT-515 and MMT-715) to receive glucose values via RF

transmission from the current BD Paradigm Link or the new LifeScan OneTouch UltraLink glucose meters is offered as a convenience to the user. Even in the event the meter and insulin pump are unable to communicate due to RF interference, the meter glucose measurement can be manually entered into the pump for use in the insulin pump's "Bolus Wizard" calculator. Since there is no risk of patient harm in the event communication is interrupted, this was not listed as risk in the DCAS provided previously. However, in response to your recent request, we have expanded the DCAS table to identify both the interruption of communication and acceptance of an incorrect glucose value as potential risks.

With respect to the risk of the insulin pump accepting a value that has been altered and therefore differs from the value measured and transmitted by the LifeScan OneTouch UltraLink meter, this risk is mitigated (and we believe eliminated) through the incorporation of robust data integrity/error checking protocols in the pump application software. Please note that there has been no change to the pump application software in association with use of Paradigm insulin pumps with the LifeScan OneTouch UltraLink meter since data is transmitted by this new meter using the same format as the previously cleared BD Paradigm Link glucose meter (K030531). As background information, a description of this protocol is provided in the following section.

Paradigm Insulin Pump Telemetry Overview

(b)(4)

(b)(4)

Design Control Activities Summary

Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Modification of pump labeling to indicate that the Medtronic MiniMed MMT-512, MMT-712, MMT-515 and MMT-715 insulin infusion pumps can receive glucose values transmitted by the LifeScan OneTouch UltraLink glucose meter (in addition to the current BD Paradigm Link glucose meter)			(b)(4)	

(b)(4)

2. You have indicated that the Paradigm pump models MMT-512, -712, -515, and -715 are to communicate with the LifeScan OneTouch Ultralink blood glucose meter. However, the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter as being a legally marketed device. Please address the following concerns.

a. The Agency believes your device product labeling can only identify communication with medical devices that have been Agency cleared. Please provide the 510(k) numbers of all medical devices with which your pump models are labeled to communicate with.

Medtronic MiniMed Response

The current labeling for the MMT-512, MMT-712, MMT-515 and MMT-715 pumps indicate that these devices can receive glucose values from the BD Paradigm Link glucose meter. The Paradigm Link meter was cleared by FDA for commercial distribution under 510(k) K030531 on June 17, 2003. The 510(k) for the LifeScan OneTouch UltraLink glucose meter is currently under review by FDA (K073261).

As previously discussed with FDA and acknowledged in our prior 510(k) supplement, we understand and agree that this 510(k) will not be cleared by FDA until FDA has cleared 510(k) K073261 for the LifeScan OneTouch UltraLink glucose meter.

b. You have provided a DCAS table that identifies testing of your pump with the LifeScan OneTouch Ultralink blood glucose meter. The Agency believes testing of your device with other medical devices should be performed on final finished devices for every device. Since the Agency is unaware of the LifeScan OneTouch Ultralink blood glucose meter being a legally marketed device, bench testing with this device cannot be performed on the final finished device. Please update your DCAS table to include testing of your device with only legally marketed (i.e., final finished device) blood glucose meters that you intend to communicate with (i.e., LifeScan OneTouch Ultralink blood glucose meter). Please certify that all testing described in the DCAS table are on final finished devices.

Medtronic MiniMed Response

As a point of clarification, in most cases, the designs of new medical devices are finalized and validation and qualification testing are conducted on final finished devices prior to submission of the approval application to FDA. Therefore, it is possible (and actually common practice) to

conduct testing with final finished devices well in advance of the new device being cleared or approved for commercial distribution by FDA.

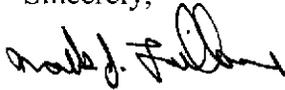
To ensure this was the case for the system level RF testing we conducted with the LifeScan OneTouch UltraLink meter, we required written assurance from LifeScan that the meters they provided to us for the system level RF testing are equivalent (with respect to RF functionality) to the version of the LifeScan OneTouch blood glucose meter that will be released for commercial distribution once FDA has cleared 510(k) K073261. Documentation to this effect is provided in this submission as Attachment 1. Please note that the LifeScan memo refers to the glucose meters provided to Medtronic MiniMed for system level RF testing as (b)(4)

(b)(4)

functionality, are equivalent to the OneTouch UltraLink meters that will be distributed following FDA clearance for commercial distribution.

I hope this additional information adequately addresses your remaining concerns. Please do not hesitate to contact me via telephone (818-576-5616) or email (mark.faillace@medtronic.com) if you require any additional information or clarification.

Sincerely,



Mark J. Faillace
Senior Director, Regulatory Affairs and Product Reporting

Attachment 1

System Level Test Unit Documentation



Memorandum

To: (b)(4)
From: (b)(4)
Date: February 4, 2007

Purpose: PF 3027608 Equivalence Documentation of meters provided to MiniMed for verification/validation testing

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Approver List

(b)(4)

(b)(4)