Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

K002138

AUG 2 9 2000

Section C. 510(k) Summary

Submitter: Maersk Medical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Maersk Contact: Mr. John M. Lindskog, General Manager, Maersk Medical A/S Infusion Devices
Telephone: + 45 48 16 70 00

U.S. Contact: Jennifer Lyons (818) 362-5958, Ext. 7381; JenniferLy@MiniMed.com

Name of Device: Paradigm™ Silhouette® infusion set, models 377, 378, 379, 380

Predicate Device: Maersk Medical Comfort Infusion Set

Description of the New Device: The Paradigm Silhouette infusion sets are infusion administration sets, connecting to a MiniMed medication reservoir developed for use with a MiniMed Paradigm infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The 25 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle made of 304 stainless steel.

Intended Use of the New Device: The Paradigm Silhouette infusion sets are intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump. The infusion sets are neither intended nor indicated for use with blood.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate device differ only in the type of connector that attaches the infusion set to a reservoir. The modification does not affect the safety or effectiveness of the device.

Signed,

John M. Lindskog 7/6/2000
John M. Lindskog date
General Manager
Maersk Medical A/S

®MiniMed and Silhouette are Registered Trademarks of MiniMed Inc.
™ Paradigm is a Trademark of MiniMed Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Maersk Medical A/S
C/O Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K002138
Trade Name: Paradigm Silhouette Infusion Set
Regulatory Class: II and II
Product Code: FPA and FPK
Dated: July 6, 2000
Received: July 17, 2000

Dear Ms. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-20-2015 K002138

INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Silhouette infusion set

Indications for Use: The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002138

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2000

Maersk Medical A/S
C/O Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K002138
Trade Name: Paradigm Silhouette Infusion Set
Regulatory Class: II and II
Product Code: FPA and FPK
Dated: July 6, 2000
Received: July 17, 2000

Dear Ms. Lyons:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center of Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

K002138

INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Silhouette infusion set

Indications for Use: The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002138

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 8/25/00

From: Reviewer(s) - Name(s) Irene Naveau

Subject: 510(k) Number K002138

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

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

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

☐ The required certification and summary for class III devices

☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☐ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with class: 80/FPA/II/880.5440

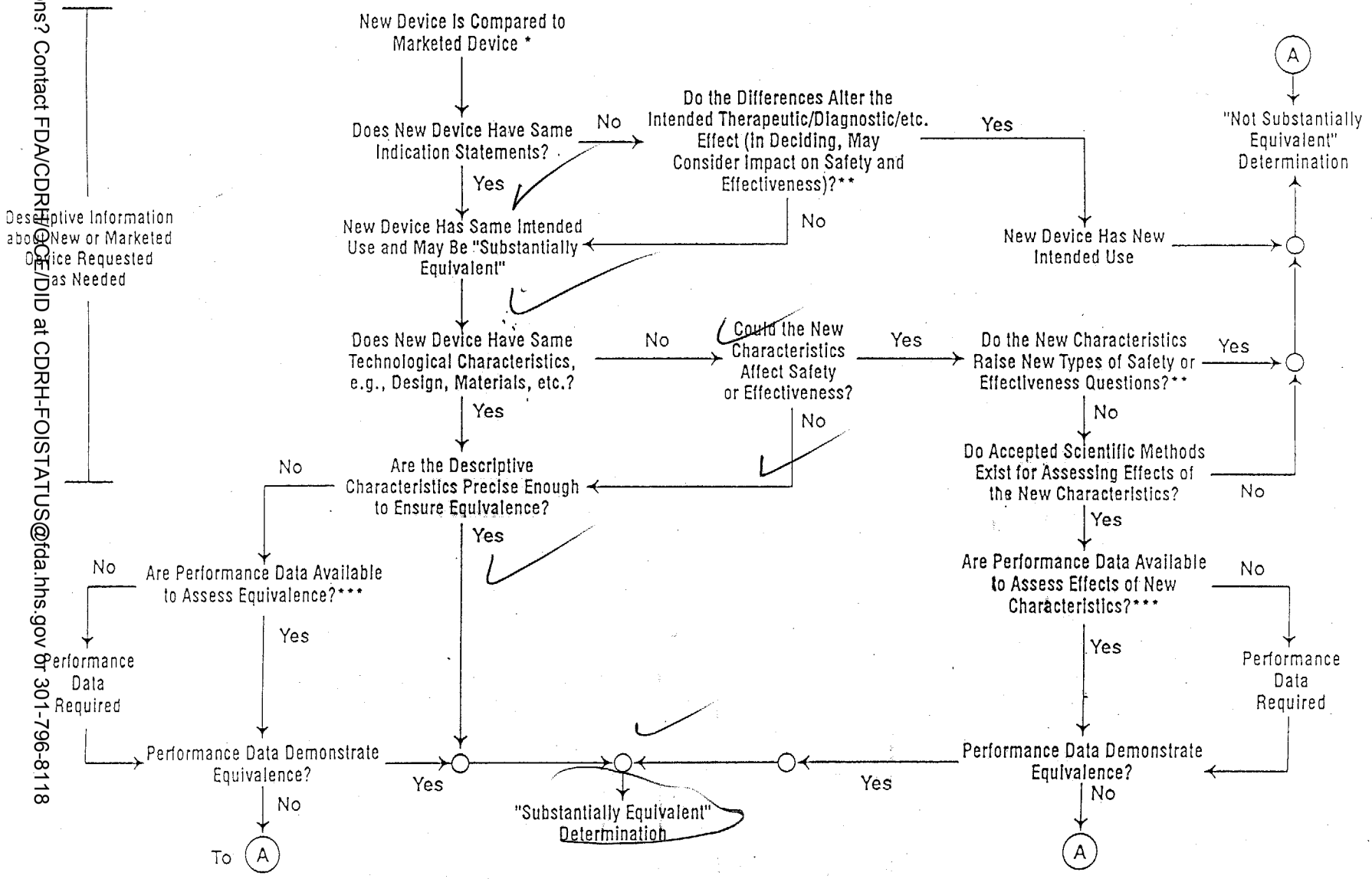
Additional Product Code(s) with panel (optional): 80/FPK/II/880.5440

Review: Patricia Cecinite (Branch Chief) — CDRH (Branch Code) — 8/28/00 (Date)

Final Review: (Division Director) — 8/29/00

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Addition[illegible]ormation If the Relationship Between Marketed and "Predicate" (Pre-Am[illegible]or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limi[illegible] Testing Information Is Sometimes Required.

*** Dat[illegible]n the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SE MEMO TO THE RECORD

510(k) REVIEW

K002138

DATE: August 25, 2000
FROM: Irene Naveau

OFFICE: HFZ-480
DIVISION: DDIG/GHDB

COMPANY NAME: Maersk Medical A/S
DEVICE NAME: Paradigm™ Silhouette® Infusion Set, Models MTT-377, 378, 379, 380

NARRATIVE DEVICE DESCRIPTION

1. SUMMARY DESCRIPTION OF THE DEVICE UNDER REVIEW:

The Paradigm™ Silhouette® Infusion Set is a sterile, single use device with two basic components: an infusion set, and a stand-alone subcutaneous indwelling catheter. The infusion set consists of a co-extruded tubing (polyethylene and polyurethane) that is proximally connected to a medication reservoir by means of a proprietary tubing connector, and a type 304 stainless steel needle incorporated into the male portion of the proprietary plastic "click-lock" connector at the patient end. The set side of the proprietary tubing connector accommodates a bond joint similar to that of a Luer connector in the predicate device. The reservoir side of the tubing connector attaches to the reservoir with a ¼ turn to provide a venting mechanism to equalize pressure in the reservoir chamber with the Paradigm infusion pump.

The catheter assembly consists of a stainless steel needle, a (b)(4) cannula, an adhesive backed fixation tape, an injection port, and the female portion of the proprietary plastic "click-lock" connector. This female portion is connected to the male portion of the proprietary connector. Refer to pictorial directions for use. The infusion set can be detached from the indwelling capped catheter to allow freedom of movement during showers and other activities.

This device is available in four models:
MMT-377—infusion set, 43 inches in length;
MMT-378-infusion set, 23 inches in length;
MMT-379-combination (Combo) set consisting of a 43 inch infusion set with catheter and disconnect cover in one package and a second single catheter in another package; and,
MMT-389-combination (Combo) set consisting of a 23 inch infusion set with catheter and disconnect cover in one package and a second single catheter in another package.

This device is designed for use with the Paradigm insulin pump, MMT-511 and the Paradigm 1.5ml reservoir, MMT-326, both of which were cleared under the 510(k) process.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Refer to Attachment 1 for complete listing of all material chemical formulations.

2. INTENDED USE: For the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

3. DEVICE DESCRIPTION:

A. Life-supporting or life-sustaining: No
B. Implant (short-term or long-term): No

C. Is the device sterile? Yes

Method	(b)(4) [redacted]
Validation	
SAL	
Dosage	
Pyrogenicity	

Packaging: (b)(4) [redacted] pack with a clear tray of rigid (b)(4) [redacted] (b)(4) [redacted], and sealed with a (b)(4) [redacted]. A package may include a catheter and tubing or a catheter, tubing, and an additional catheter.

D. Is the device for single use? Yes
E. Is the device for prescription use? Yes
F. Is the device for home use or portable? Yes

G. Does the device contain drug or biological product as a component? No
H. Is this device a kit? No
I. Software-driven? No
J. Electrically Operated? No
K. Applicable standards to which conformance has been demonstrated (e.g., IEC, ANSI, ASTM, etc.): N/A
L. Device(s) to which equivalence is claimed, manufacturer, and 510(k) number or preamendment status: Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Set, Maersk Medical Inc., K972135.

M. Submission provides

comparative specifications	a	Yes
compatative in vitro data	b	No
performance data	c	No
animal testing	d	No
clinical testing	e	No
biocompatibility testing	f	No

The sponsor certifies that all testing and qualification for the Paradigm™ Silhouette® Infusion Set will be completed in accordance with test plans provided to the FDA before any device is delivered to the marketplace. The infusion set will be tested (b)(4) [redacted]

The sponsor further certifies that the Paradigm™ Silhouette® Infusion Set will conform to FDA recognized standard ISO 10993-1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

before any device is delivered to the marketplace.

N. Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

The Paradigm™ Silhouette® Infusion Set is a modification of the Maersk Comfort Infusion Set. Both sets are used for the subcutaneous delivery of insulin or other appropriately labeled medications from a reservoir/infusion pump. The materials, tubing lengths, hubs, adhesives, needles and catheters are identical. The difference in the infusion sets is the (b)(4) [redacted] (b)(4) [redacted]

In a telephone conversation with Ms. Jennifer Lyons, Regulatory Affairs Specialist on July 31, 2000, I requested that the (b)(4) [redacted] (b)(4) [redacted] I also requested the (b)(4) [redacted] Ms. Lyons responded adequately.

The labeling, with minor revision, is adequate for this device. The sponsor has included the following in the instructions for use portion of the labeling: priming volume, tubing inner and outer diameters, and a non-pyrogenic statement. The instructions for use are clear and concise, and include pertinent information for the use of this device with insulin. The labeling includes appropriate warnings, precautions, adverse reactions, and contraindications for use. Pictorials are included with the instructions for use.

Based on the information provided by in this premarket notification, I believe that this device is substantially equivalent to the predicate device listed in Section L. No new issues of safety or effectiveness exist for this device.

O. Does the submission include a summary of safety and effectiveness information upon which an equivalence determination is based? Yes

P. RECOMMENDATION:

I believe that this device is equivalent to: 80 FPA/FPK

Classification should be based on: Intravascular Administration Set/Fluid Delivery Tubing

880.5440 Class: II

Irene Naveau 8/25/00 IPC 8/28/00

Irene Naveau

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K002138

Reviewer: Irene Naveau

Division/Branch: DDIGD/GHDB

Device Name: Paradigm™ Silhouette® Infusion Set, Models MTT-377, 378, 379, 380.

Product To Which Compared (510(K) Number If Known): Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Set, Maersk Medical Inc., K972135.

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

1. Intended Use: For the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

2. Device Description: Refer to SE Memo dated August 25, 2000.

5. Describe the new technological characteristics: This device has a new proprietary (b)(4) [redacted]

6. Explain how new characteristics could or could not affect safety or effectiveness: This new characteristic will not adversely affect the safety or effectiveness of this device, but will establish fluid flow through the connector. It does not affect the basic characteristic of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1C 002138/A1

MiniMed®

August 3, 2000

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

Re: 510(k) Notification for the Paradigm Silhouette (K002138); Additional Information, as requested

Dear Ms. Naveau:

Enclosed is the sample of the Paradigm Silhouette infusion set you requested during our telephone conversation on July 31, 2000. This particular sample is a 43 in. full set, model 377. Maersk Medical has provided the additional information you requested.

Should you require additional information, please do not hesitate to contact me at (818) 362-5958, Ext. 7381.

Sincerely,

Jennifer Lyons

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.

SK-18

Enc (1): Sample

cc: (b)(6) [redacted] Manager, Regulatory Affairs
(b) [redacted] Senior Director, Clinical and Regulatory Affairs

FDA/CDRH/ODE/DMC
4 AUG 00 11 23
RECEIVED

10

12744 San Fernando Road • Sylmar, CA 91342 • (800) 933-3322 • (818) 362-5958 • FAX (818) 364-2246 • Web Site: http://www.minimed.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

K 002138/A2

MAERSK

FDA/CDRH/OCE/DID

4 Aug 00 13 15

SK' 30

August 2, 2000

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

Re: 510(k) Notification for the Paradigm Silhouette (K002138); Additional Information, as requested

Dear Ms. Naveau:

Following is the information you requested for the Paradigm Silhouette infusion sets.

(b)(4)

[redacted]

®MiniMed and Silhouette are Registered Trademarks of MiniMed Inc.
™Paradigm is a trademark of MiniMed Inc.

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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If you have additional question, please contact Jennifer Lyons, who may be reached, via MiniMed Inc. at (818) 362-5958, Ext. 7381. Her mailing address is Regulatory Affairs, MiniMed Inc., 12744 San Fernando Road, Sylmar, CA 91342.

Sincerely,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

Enc (4): (b)(4) [redacted]

cc: Jennifer Lyons; Regulatory Affairs, MiniMed Inc.

CONFIDENTIAL

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAERSK

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Attachment 5	Drawing of Catheter & Bush part	9

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 13

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

Attachment 1. Materials Matrix

Components and materials: Following is a list of the principal components of the Paradigm Silhouette infusion set:

Part number	Part Description	Material and Formulation	Contact type
1	Needle protector	(b)(4) [redacted]	None
2	Introducer needle		Direct - tissues
3	Catheter		Direct - tissues
4	Fixation tape (Dressing/glue)		Direct - skin
5	Cannula housing		None
6	Introducer needle hub		None
7	Teflon bush		Indirect - fluid path
8	Injection port		Indirect - fluid path
9	Segment		None
10	Connector needle		Indirect - fluid path
11	Connector hub (luer lock)		Indirect - fluid path
12	Tubing (inner/outer)		Indirect - fluid path / direct - skin
13	UV cure adhesive		None
14	Tubing Connector		Indirect - fluid path
	Tubing Connector needle		Indirect - fluid path
	Venting membrane		None
	UV Cure adhesive		None
15	Cannula Housing protector		None

The part numbers are also shown in appendix 6 (Engineering drawing).

ii. Other materials: The materials listed below are also used in the fabrication of the Paradigm Silhouette:

Material	Comments
(b)(4) [redacted]	Used as a lubricant for the needle.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2. Sterilization Residues

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

15

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Attachment 3. Biocompatibility Certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

MAERSK

BIOCOMPATIBILITY CERTIFICATION

As a responsible official of Maersk Medical A/S, I hereby certify that the Paradigm Silhouette infusion set will conform to FDA recognized standard ISO 10993-1 before any device is delivered to the marketplace.

Signed,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

Date
8/2/2000

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

Attachment 4. Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAERSK

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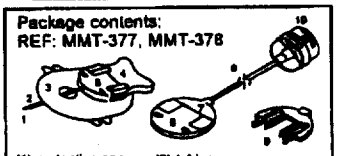
paradigm

Silhouette® INFUSION SET

Instructions for Use

Package contents:
REF: MMT-377, MMT-378



(1) protective cap
(2) soft cannula (250 x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing
(6) tubing
- inner diameter = .015 in. (.38 mm)
- outer diameter = .059 in. (1.5 mm)

(7) connector needle
(8) circular protective cap
(9) disconnect cover
(10) tubing connector

Silhouette Combo
REF: MMT-379, MMT-380

Package A contents:
(1) protective cap
(2) soft cannula (250 x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing
(6) tubing
(7) connector needle
(8) circular protective cap
(9) disconnect cover
(10) tubing connector

Package B contents:
(1) protective cap
(2) soft cannula (250 x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing

Remark: This version allows you to change the soft cannulas twice for every tubing used. For the first time, use a soft cannula and a tubing (see above package A).

STERILE DEVICE
This device is sterile and non-pyrogenic unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged.

PRECAUTIONS
- Read instructions for use carefully before handling Paradigm Silhouette.
- If using Paradigm Silhouette for the first time, do your first-set up in the presence of your healthcare professional.
- If using insulin, check blood glucose 1 to 3 hours after insertion and re-check blood glucose levels frequently during the day according to your healthcare professional's recommendation.
- The numbers in the text refer to the package contents diagram.

INDICATIONS FOR USE
The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a Minimed Paradigm infusion pump.

CONTRAINDICATIONS
The Paradigm Silhouette infusion sets are contraindicated for the infusion of blood.

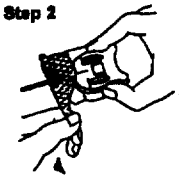
ADVERSE REACTIONS
Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of an infusion site. Users are advised to review carefully the directions for inserting and securing the infusion set.

INSERTING THE PARADIGM SILHOUETTE

Step 1

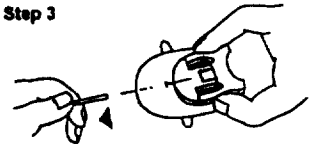
Prepare the skin at the infusion site. Select a site away from the belt line to keep the soft cannula from getting dislodged and to prevent irritation. The injection site should be cleaned thoroughly and allowed to dry before the Paradigm Silhouette is inserted.

Step 2



Remove the front half of the backing paper from the white adhesive tape (3).

Step 3

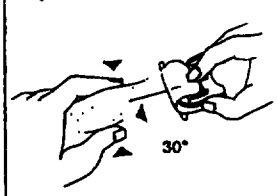


Remove the plastic protective cap (1) from the needle.

Step 4

Hold the Paradigm Silhouette as shown in the Figure above, using the index finger to hold back the forward flap of the white adhesive tape (3).

Step 5



With the other hand, pinch the subcutaneous tissue as you would to give an injection. Push the needle with a firm motion into the infusion site at a 30 degree angle.

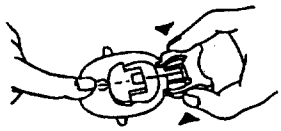
Important: People with small or large amounts of subcutaneous fat should be careful when choosing the insertion angle because the cannula could be placed in the underlying muscle layer or in the dermal layer and therefore cause reduced or blocked medication delivery (check with your healthcare professional regarding this point).

Make sure that the soft cannula is well inserted into the subcutaneous tissue.

Step 6

Carefully smooth out the front half of the adhesive tape (3) onto the skin.

Step 7

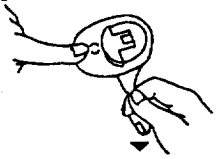


To remove the introducer needle (4), put one finger just in front of the see-through window to keep Paradigm Silhouette in place and with your other hand, press gently the side clips with two fingers while simultaneously withdrawing the introducer needle.

Note: The introducer needle (4) goes through a clear tube, called the soft cannula (2) which is what remains in the subcutaneous layer after the introducer needle is removed.

Remark: Dispose of the introducer needle (4) in a safe manner in a sharps container.

Step 8



Remove the back side of the backing paper and smooth out the white adhesive tape (3) to make sure good skin contact is achieved.

Vendor to use Electronic File

SH 1/2 DMP9195851-011 REV B

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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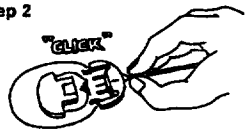
MAERSK

CONNECTING THE PARADIGM SILHOUETTE

Step 1

Attach the tubing connector (10) to the reservoir and pump according to the Paradigm pump User's Guide. Remove the circular protective cap (8) at the end of the tubing by gently pressing the side clips of the connector needle (7). Follow the Paradigm pump User's Guide to prime the set. Prime the tubing (6) until medication drips from the connector needle (7). The priming volume is approximately 0.10 ml for the 23" set (for insulin, 10 units of U-100) and 0.16 ml for the 43" set (for insulin, 16 units of U-100).

Step 2



Hold the connector needle (7) with the rounded side facing up and insert it into the cannula housing (5) until you hear an audible "click".

Important: Give a slight pull on the tubing (6) to check if the two parts are well connected.

Remark: Keep the circular protective cap (8) and the disconnect cover (9) in the individual blister pack (click the two pieces together). You will need these pieces if you intend to disconnect.

PRECAUTIONS

It is generally advisable to administer a bolus of at least 0.0075 ml (for insulin: 0.5-1 unit of U-100) to fill the empty space in the soft cannula after the introducer needle is withdrawn. Follow the recommendation of your healthcare professional.

Made for:

MiniMed

USA:
Sylmar, CA
818-362-5958 • 800-826-2098 (24-hour Help Line within U.S. & Canada)
818-676-5555 (outside U.S.)

To order supplies:
800-843-6697 • Fax: 866-268-9200 (within U.S. & Canada)
Fax: 818-362-3788 (outside U.S.)

Made in Denmark by: Maersk Medical A/S, DK-4000

These products are covered by one or more of the following U.S. or foreign patents: [U.S.] 5,522,803
Other U.S. and/or foreign patents may be pending.

Silhouette is a registered trademark of MiniMed Inc.
Paradigm is a trademark of MiniMed Inc.

D9195851-011 9/00 0301 CE

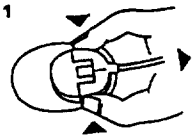
DISCONNECTING THE PARADIGM SILHOUETTE

The Paradigm Silhouette allows you the freedom to temporarily disconnect from your pump for showers, swimming etc., without changing your infusion set.

PRECAUTION

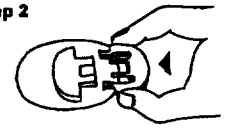
Please consult with your healthcare professional on how you should compensate for any missed medication when you are disconnected. If using insulin, carefully monitor blood glucose levels when you are disconnected from the pump and after you re-connect to the pump.

Step 1



Remove the tubing (6) by gently pressing the side clips of the connector needle (7) as shown. Use the circular protective cap (8) to protect the connector needle (7).

Step 2



Insert the disconnect cover (9) into the cannula housing (5) until you hear an audible "click".

Important:
Before re-connecting, ensure that a drop of insulin or medication appears at the tip of the connector needle (see step 2 - Connecting the Paradigm Silhouette).

SYMBOL	MEANING
	EXPIRATION DATE
	DO NOT RE-USE
	READ INSTRUCTIONS FOR USE
LOT	LOT NUMBER
STERILE EO	STERILIZED WITH ETHYLENE OXIDE
REF	REFERENCE/MODEL NUMBER
	OPEN HERE

WARNINGS

- A small percentage of soft cannula sets may crimp upon insertion or become dislodged during use.
- Do not leave air in infusion set. Prime completely.
- Use aseptic techniques when temporarily disconnecting the set. Be certain to cap the tubing and the cannula housing with the cover provided.
- Replace the Paradigm Silhouette if the dressing tape comes loose, because the soft cannula may be half way out or dislodged.
- If the infusion site becomes inflamed, replace the set and use a new site until the first site has healed.
- Do not put disinfectants, perfumes, or deodorants on your infusion set as these may affect the integrity of the set.
- Never prime the set or attempt to free a clogged line while the infusion set is inserted. You may accidentally inject too much medication.
- Do not reinsert the introducer needle into the infusion set. Re-insertion could cause tearing of the soft cannula which would result in unpredictable medication flow.
- Replace the infusion set according to CDC (Centers for Disease Control) guidelines (every 72 hours) or institutional protocol.
- For subcutaneous use only, not for IV (intravenous) infusion.
- Dispose of properly after single use. Do not clean or re-sterilize.
- CAUTION: U.S. law restricts this device to sale by or on the order of a physician.

If you are using insulin:

- Check frequently to make sure the soft cannula remains firmly in place. Because the cannula is so soft, you will not notice any pain if it pulls out. The soft cannula must always be completely inserted so that you receive the full amount of medication.
- Check blood glucose level 1 to 3 hours after inserting a Paradigm Silhouette and monitor the infusion site by using the see-through window integrated in the white dressing tape. Check blood glucose frequently (check with your physician).
- Do not insert a new soft cannula just prior to bedtime, unless blood glucose can be checked 1-3 hours after insertion.
- If your blood glucose level becomes unexplainably high, or an "occlusion" alarm occurs, check for clogs and leaks. If in doubt, change infusion set: the soft cannula could be dislodged or partially clogged.

  *Check blood glucose one hour after changing Paradigm Silhouette and test again more often to make sure you have corrected the problem.
  *If still high, contact your physician immediately.
  *If your physician is not available, inject insulin manually per your physician's recommendation.
- Preventing hyperglycemia - Prevention is your responsibility. Therefore, discuss with your physician a plan of action for rapid replacement of insulin should your soft cannula become dislodged.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

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Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Paradigm Silhouette, Model MMT-377 | K002138

Submitter (Company): Maersk Medical A/S

Items which should be included (circle missing & needed information)	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as: a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)	GO TO # 2,3		GO TO # 2,4,5		GO TO #2 4,5	✓	

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA		YES		NO		✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)	SPECIALS		ABBREVIATED		TRADITIONAL		
	YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class					✓		
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA				✓		
d) compliance with Section 514 - performance standards	NA				✓		
e) address of manufacturer					✓		
f) Truthful and Accurate Statement					✓		
g) Indications for Use enclosure					✓		
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					✓		
k) Proposed Labeling:					✓		
i) package labeling (user info)					✓		
ii) statement of intended use					✓		
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					✓		
i) Labeling					✓		
ii) intended use					✓		
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE				
a) Name & 510(k) number of legally marketed (unmodified) predicate device				
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*			* If no - STOP not a special	

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USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) ***STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED****			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) 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				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) 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				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

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inapplicable requirements or deviations noted below					
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed					
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device					
v) A specification of any deviations from each applicable standard that were applied					
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference					
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations					
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards					

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ **Yes** ____ **No** **Reviewer:** _____

Date: JUL 20 2000 **Concurrence by Review Branch:** _____

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

Internal Administrative Form

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

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

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

July 18, 2000

MAERSK MEDICAL A/S
C/O MINIMED INC
12744 SAN FERNANDO ROAD
SYLMAR, CA 91342
ATTN: JENNIFER LYONS

510(k) Number: K002138
Received: 17-JUL-2000
Product: PARADIGM SILHOUETTE, MODELS MMT-377, 378, 379, 380

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

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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 Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1C002138

CDRH SUBMISSION COVER SHEET

Date of Submission: **June X, 2000**	FDA Document Number:

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
Original Submission Modular Submission Amendment Report Report Amendment	Regular Special Panel Track 30-day Supplement 30-day Notice 135-day Supplement Real-time Review Amendment to PMA Supplement	Presubmission Summary Original PDP Notice of intent to start clinical trials Intention to submit Notice of Completion Notice of Completion Amendment to PDP Report	Original Submission: Traditional Special Abbreviated Additional Information Traditional Special Abbreviated	Pre-IDE Meeting Pre-PMA Meeting Pre-PDP Meeting 180-day Meeting Other (specify):
IDE	**Humanitarian Device Exemption**	**Class II Exemption**	**Evaluation of Automatic Class III Designation**	**Other Submission**
Original Submission Amendment Supplement	Original Submission Amendment Supplement Report	Original Submission Additional Information	Original Submission Additional Information	Describe Submission:

Section B — Applicant or Sponsor

Company/Institution Name: **Maersk Medical A/S**		Establishment Registration Number: **8021545**
Division Name (If Applicable): **Infusion Devices**		Phone Number (Include Area Code): **(+45) 48 16 70 00**
Street Address: **Aaholmvej 1-3**		Fax Number (Include Area Code): **(+45) 46 42 78 65**
City: **Osted**	State/Province: **DK-4000 Roskilde**	Country: **Denmark**
Contact Name: **John M. Lindskog**		
Contact Title: **General Manager, Infusion Devices**		Contact E-Mail Address: **jml@maersk-medical.com**

Section C — Submission Correspondent (if different from above)

Company/Institution Name: **MiniMed Inc.**		Establishment Registration Number:
Division Name (If Applicable):		Phone Number (Include Area Code): **(818) 362-5958**
Street Address: **12744 San Fernando Road**		Fax Number (Include Area Code): **(818) 772-1114**
City: **Sylmar**	State/Province: **California**	Country: **USA**
Contact Name: **Jennifer Lyons**		
Contact Title: **Regulatory Affairs Specialist**		Contact E-Mail Address: **Jenniferly@minimed.com**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section D1 Reason for Submission — PMA, PDP, or HDE

New Device
Withdrawal
Additional or expanded indications
Licensing agreement

Process change:
- Manufacturing
- Sterilization
- Packaging
- Other (specify below)

Response to FDA Correspondence
- Request for applicant hold
- Request for removal of applicant hold
- Request for extension
- Request to remove or add manufacturing site

Other reason (specify):

Change in design, component, or specification:
- Software
- Color Additive
- Material
- Specifications
- Other (specify other)

Labeling change:
- Indications
- Instructions
- Performance Characteristics
- Shelf life
- Trade name
- Other (specify below)

Location change:
- Manufacturer
- Sterilizer
- Packager
- Distributor

Report submission:
- Annual or periodic
- Post-approval study
- Adverse reaction
- Device defect
- Amendment

Change in ownership
Change in correspondent

Section D2 Reason for Submission —IDE

New Device
Addition of institution
Expansion/extension of study
IRB certification
Request hearing
Request waiver
Termination of study
Withdrawal of application
Unanticipated adverse effect
Notification of emergency use
Compassionate use request
Treatment IDE
Continuing availability request

Other reason (specify):

Change in:
- Correspondent
- Design
- Informed consent
- Manufacturer
- Manufacturing process
- Protocol - feasibility
- Protocol - other
- Sponsor

Report submission:
- Current investigator
- Annual progress
- Site waiver limit reached
- Final

Response to FDA letter concerning:
- Conditional approval
- Deemed approved
- Deficient final report
- Deficient progress report
- Deficient investigator report
- Disapproval
- Request extension of time to respond to FDA
- Request meeting

Section D3 Reason for Submission — 510(k)

New Device
Additional or expanded indications
Other reason (specify):

Change in technology
Change in design

Change in materials
Change in manufacturing process

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8218

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed			Summary of statement concerning, safety and effectiveness data: 510(k) summary attached 510(k) statement
1 **80FPA**	2	3	4
5	6	7	8

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 **K972135**	1 **Pureline Comfort**	1 **Maersk Medical**
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F — Product Information – Applicable to All Applications

Common or usual name or classification name: **Subcutaneous Infusion Administration Set**

Trade or Proprietary or Model Name	Model Number
1 **Paradigm Silhouette**	1 **Models MMT-377, 378, 379, 380**
2	2
3	3
4	4
5	5

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

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

Data included in submission: Laboratory testing Animal trials Human trials

Section G — Product Classification – Applicable to All Applications

Product Code: **80FPA; 80FPK**	C.F.R. Section: **880.5440**	Device Class: Class I Class II Class III Unclassified

Classification Panel: **General Hospital and Personal Use Panel: (80)**

Indications (from labeling): **The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.**

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

Section H **Manufacturing/Packaging/Sterilization Sites Relating to a Submission**

Original Add Delete	FDA Establishment Registration Number:	**Manufacturer** Contract Manufacturer	Contract Sterilizer Repackager/Relabeler
Company/Institution Name: **Maersk Medical**		Establishment Registration Number: **8021545**	
Division Name (If Applicable): **Infusion Devices**		Phone Number (Include Area Code): **(+45) 48 16 70 00**	
Street Address: **Aaholmvej 2**		Fax Number (Include Area Code): **(+45) 46 42 78 65**	
City: **Osted**	State/Province: **DK-4000 Roskilde**	Country: **Denmark**	
Contact Name: **John M. Lindskog**			
Contact Title: **General Manager, Infusion Devices**		Contact E-Mail Address:	
Original Add Delete	FDA Established Registration Number:	Manufacturer Contract Manufacturer	**Sterilizer** Repackager/Relabeler
Company/Institution Name: **Maersk Medical**		Establishment Registration Number: **9611233**	
Division Name (If Applicable): **Catheters**		Phone Number (Include Area Code): **(+45) 48 16 70 00**	
Street Address: **Unovej 1**		Fax Number (Include Area Code):	
City: **Hundested**	State/Province: **DK-3390**	Country: **Denmark**	
Contact Name:			
Contact Title:		Contact E-Mail Address:	
Original Add Delete	FDA Established Registration Number:	Manufacturer Contract Manufacturer	Contract Sterilizer Repackager/Relabeler
Company/Institution Name:		Establishment Registration Number:	
Division Name (If Applicable):		Phone Number (Include Area Code): ( )	
Street Address:		Fax Number (Include Area Code): ( )	
City:	State/Province:	Country:	
Contact Name:			
Contact Title:		Contact E-Mail Address:	

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MAERSK MEDICAL

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

MAERSK

July 6, 2000

Re: **510(k) Notification** for the Maersk Medical A/S Paradigm™ Silhouette® infusion set, models 377, 378, 379, 380

Dear Sir or Madam:

Pursuant to the requirements of Section 510(k) of the Federal Food, Drug and Cosmetic Act, notification is made of the intention of Maersk Medical A/S to introduce to the marketplace a modified version of the Maersk Medical Comfort Infusion Set Models 89-110-2622; 89-060-2622; 87-110-2652; 87-060-2652 cleared through premarket notification K972135 and marketed by MiniMed® Inc. as the Silhouette infusion set, models MMT-371, 373, 372, 374. The new infusion set will be marketed exclusively by MiniMed Inc. as the Paradigm Silhouette infusion set, models 377, 378, 379, 380.

A detailed description of the new device is enclosed, as are prototype labels and labeling. Labels and labeling of the predicate device are also enclosed.

In response to requirements of the SMDA of 1990, included is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

This 510(k) Notification is formatted as outlined in the guidance document "Premarket Notification 510(k): Regulatory Requirements for Medical Devices, 95-4158." Additionally, an annotated copy of the checklist from the March, 1995 document "Center for Devices and Radiological Health's Premarket Notification for 510(k) Refuse to Accept Checklist" is provided.

Should you require additional information, please do not hesitate to contact the undersigned.

Our U.S. contact for this submission is Jennifer Lyons, who may be reached, via MiniMed Inc. at (818) 362-5958, Ext. 7381. An E-mail message may be sent to Ms. Lyons at JenniferLy@MiniMed.com. Her mailing address is Regulatory Affairs, MiniMed Inc., 12744 San Fernando Road, Sylmar, CA 91342.

Sincerely,

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

RECEIVED
11 JUL 00 10 00
FDA/CDRH/OCE/DMC

Contents: 510(k) Notification - Original and two copies

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™ Paradigm is a trademark of MiniMed Inc.

Confidential

Maersk Medical A/S, Åholmvej 2, Osted, 4000 Roskilde, Denmark
Telephone: +45 48 16 70 00, Telefax: +45 46 49 81 70
Reg. No. 15 34 01

Questions? Contact FDA/CDRH/OCE/DID at 510(k)STATUS@fda.hhs.gov or 301-796-8118

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Section A. Annotated Checklist for Acceptance

Question	Yes	No	N/A	
I. Critical Elements				
A. Is the product a device?	_X_	___	___	
B. Is the device exempt from 510(k) by regulation or policy?	___	_X_	___	
C. Is the device subject to review by CDRH?	_X_	___	___	
D. Are you aware of this device being the subject of a previous NSE decision?	___	_X_	___	
E. Are you aware of the submitter being the subject of an integrity investigation?	___	_X_	___	
F. Does the submission contain the information required?				Page
Device trade name	_X_	___	___	___
Device common name	_X_	___	___	___
Establishment registration number	_X_	___	___	___
Device classification	_X_	___	___	___
Classification panel	_X_	___	___	___
Section 514 action	_X_	___	___	___
Proposed labels, labeling	_X_	___	___	___
510(k) Summary/Statement	_X_	___	___	___
Photographs/drawings of the device	_X_	___	___	___
Engineering drawings	_X_	___	___	___
Labeling of predicate	_X_	___	___	___
Statement of similarities and/or differences	_X_	___	___	___

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Checklist for Acceptance - Continued

Question	Yes	No	N/A	Page
Data re: modified device	_X_	___	___	___
Truthful and Accurate Statement	_X_	___	___	___
Indications for Use statement	_X_	___	___	___
II. Additional necessary information				
A. Submitter's name/address	_X_	___	___	___
B. Contact person information	_X_	___	___	___
C. Representative/consultant	_X_	___	___	___
D. Table of Contents	_X_	___	___	___
E. Address of Mfg. facility	_X_	___	___	___
III. Additional information				
A. Comparison table	_X_	___	___	___
B. Voluntary standards action	_X_	___	___	___
C. Performance Data	_X_	___	___	___
D. Sterilization information	_X_	___	___	___
E. Software information	___	___	_X_	___
F. Hardware information	___	___	_X_	___
G. Kit certification statement	__	___	_X_	___
H. Guidance document issues	_X_	___	___	___

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Section B. 510(k) Summary Checklist

Requirement	Yes	No	N/A
1. Separate section of the submission	_X_	___	___
2. Submitter information; date	_X_	___	___
3. Identification of new device	_X_	___	___
4. Identification of predicate device	_X_	___	___
5. Description of new device	_X_	___	___
6. Intended use of new device	_X_	___	___
7. Summary of comparison of technological characteristics	_X_	___	___
8. Discussion of nonclinical data, if any	___	___	_X_
9. Conclusions from clinical/nonclinical studies, if any	___	___	_X_
10. Contents of summary:			
a. All information is contained in the submission	_X_	___	___
b. No unsubstantiated labeling claims	_X_	___	___
c. No raw data; only summaries	_X_	___	___
d. No trade secret/confidential information	_X_	___	___
e. No patient identification information	_X_	___	___

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section C. 510(k) Summary

Submitter: Maersk Medical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Maersk Contact: Mr. John M. Lindskog, General Manager, Maersk Medical A/S Infusion Devices
Telephone: + 45 48 16 70 00

U.S. Contact: Jennifer Lyons (818) 362-5958, Ext. 7381; JenniferLy@MiniMed.com

Name of Device: Paradigm™ Silhouette® infusion set, models 377, 378, 379, 380

Predicate Device: Maersk Medical Comfort Infusion Set

Description of the New Device: The Paradigm Silhouette infusion sets are infusion administration sets, connecting to a MiniMed medication reservoir developed for use with a MiniMed Paradigm infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The 25 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle made of 304 stainless steel.

Intended Use of the New Device: The Paradigm Silhouette infusion sets are intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump. The infusion sets are neither intended nor indicated for use with blood.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate device differ only in the type of connector that attaches the infusion set to a reservoir. The modification does not affect the safety or effectiveness of the device.

Signed,

John M. Lindskog 7/6/2000
date

John M. Lindskog
General Manager
Maersk Medical A/S

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™ Paradigm is a Trademark of MiniMed Inc.

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Section D. Certifications

1. Truthful and Accurate Statement

2. Indications for Use Statement

3. Product Testing and Qualification Certification

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

I hereby certify, as a responsible representative of Maersk Medical A/S, that I believe to the best of my knowledge and understanding, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

7/6/2000

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

date

Premarket Notification [510(k)] Number

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 42

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INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Silhouette infusion set

Indications for Use: The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 43

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PRODUCT TESTING AND QUALIFICATION CERTIFICATION

As a responsible official of Maersk Medical A/S, I hereby certify that all testing and qualification for the Paradigm Silhouette infusion set will be completed in accordance with test plans provided to the FDA before any device is delivered to the marketplace.

Signed,

7/6/2000

John M. Lindskog
General Manager
Maersk Medical A/S
Infusion Devices

date

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 44

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Section E. Submitter Information

1. Applicant

Maersk Medical A/S
Infusion Devices
Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark

2. Contact Person

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.
(818) 362-5958, Ext. 7381
FAX: (818) 772-1114
Internet: JenniferLy@MiniMed.com

3. Representative/Consultant

Jennifer Lyons
Regulatory Affairs Specialist
MiniMed Inc.
(818) 362-5958, Ext. 7381
FAX: (818) 772-1114
Internet: JenniferLy@MiniMed.com

4. Establishment Registration Number

8021545

5. Address of Manufacturing Site

Maersk Medical A/S
Infusion Devices
Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark

6. Purpose of the Submission

This submission describes a device which is a modification of the Maersk Comfort infusion set, cleared through premarket notification K972135 and marketed by MiniMed Inc. as the Silhouette infusion set, to be named the Paradigm Silhouette infusion set.

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The modification that results in the new infusion set is a (b)(4) [redacted] (b)(4) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 46

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Section F. Description of the New Device

1. Device Trade or Proprietary Name

Paradigm Silhouette infusion set

2. Device Common and Classification Name(s)

Common Name:	Subcutaneous Infusion Administration Set
Classification Name:	Intravascular Administration Set
	Fluid Delivery Tubing

3. Device Classification Information

Class:	II
Panel:	80
Product Code:	80FPA; 80FPK
Cite:	21 CFR 880.5440

4. Description of the New Device

a. Type of device: The Paradigm Silhouette infusion sets, models 377, 378, 379, 380, are infusion administration sets, connecting to a MiniMed Paradigm medication reservoir. The infusion set is inserted in the subcutaneous tissue of a user.

There are two basic components of the device. The first is a stand-alone subcutaneous indwelling catheter. The catheter is provided as an integral assembly with a (b)(4) cannula, adhesive backed fixation tape, an injection port, and the female portion of a proprietary plastic "click-lock" connector. The catheter assembly comes with a stainless steel insertion needle.

The insertion cannula is mounted to a male portion of the proprietary plastic "click-lock" connector. The cannula is inserted through the injection port and the inner lumen of the (b)(4) catheter with the needle end protruding past the tip of the catheter for insertion into the subcutaneoum. The male connector is locked to the female connector on the indwelling catheter. A needle protector is assembled over the (b)(4) catheter and the insertion cannula. In order to maintain the sterility of the infusion path, the male "click-lock" connector comes attached to a mating female connector.

A separate male portion of the proprietary "click-lock" connector without the insertion cannula is provided in the package. These components are used to attach to the female connector of the catheter after the indwelling (b)(4) cannula has

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been inserted and the steel insertion cannula has been withdrawn. The connector protects the indwelling catheter when the infusion set is not attached.

The second component of the Paradigm Silhouette infusion set is the infusion set proper. The infusion set is comprised of a co-extruded tube with a tubing connector at the reservoir end and a stainless steel needle incorporated into the male portion of the proprietary plastic "click-lock" connector at the patient end.

The set side of the proprietary MiniMed tubing connector is designed to accommodate a bond joint which is similar to that on the Luer connector of the predicate device. The reservoir side of the tubing connector attaches to the reservoir connector with a ¼ turn 'snap and lock'. This is intended to provide feedback of correct connection. A tubing connector needle is used to pierce the reservoir septum. This connection will establish the fluid path to the reservoir, and will withstand inadvertent disconnect when locked. In addition to being a single use device, the infusion set is intended for a single puncture of the reservoir. The connected set and reservoir will install in a MiniMed Paradigm infusion pump with a ½ to 1 turn.

The tubing connector provides a venting mechanism to equalize pressure in the reservoir chamber within the MiniMed Paradigm pump. The venting mechanism will allow equalization of a pressure differential created by an altitude change between sea level and 10,000 ft air within 10 minutes, will withstand 8 ft of water for 30 minutes, and have a dry out time of 10 minutes or less.

The indwelling catheter can be inserted independently from the infusion catheter and can be accessed for injections through the injection port. The indwelling catheter can also be securely attached to the catheter by means of a proprietary "click-lock" connector for the infusion of medication subcutaneously. The infusion set can be detached from the indwelling catheter, and the catheter capped, to allow freedom from the infusion set and pump for showers, athletics, or other activities.

Paradigm Silhouette Full Sets, MMT-377 and MMT-378, are full infusion sets consisting of either 23 in. or 43 in. long tubing with catheter and disconnect cover. Paradigm Silhouette "Combo" (combination) infusion sets, MMT-379 and MMT-380, consist of a full 23 in. or 43 in. set with catheter and disconnect cover in one package and a second single catheter in another package. The combination of the Full and Combo sets and the two tubing lengths results in four models of the device:

Model Number	Set Type	Tubing length
MMT-377	Full set	43 in
MMT-378	Full set	23 in
MMT-379	Combo set	43 in
MMT-380	Combo set	23 in

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 48

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b. Statement of intended use: The Paradigm Silhouette infusion set is intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump. The set is not intended nor indicated for use with blood.

c. Use with other devices: The new infusion set will be marketed exclusively by MiniMed Inc. for use with the following MiniMed products:

Model Name/Number	Device Type
Paradigm insulin pump, MMT-511*	Insulin Infusion Pump
Paradigm 1.5ml reservoir, MMT-326*	User-filled Reservoir

* Premarket notification has been submitted.

Other infusion pumps and reservoirs are in development by MiniMed Inc. and may be designed for use with the Paradigm Silhouette infusion set.

d. Physical specifications

i. Components and materials: Following is a list of the principal components of the Paradigm Silhouette infusion set:

Part Description	Material
Tubing Connector	(b)(4) [redacted]
Tubing Connector needle	
Tubing Connector vent	
Needle protector	
Introducer needle	
Catheter	
Fixation tape	
Cannula housing	
Introducer needle hub	
Teflon bush	
Injection port	
Segment	
Connector needle	
Connector hub	
Tubing (inner/outer)	

ii. Other materials: The materials listed below are also used in the fabrication of the Paradigm Silhouette:

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Material	Comments
(b)(4) [redacted]	Used as a lubricant for the needle.
(b)(4) [redacted] adhesive	Used to attach the female ring connector to the tubing distally, the tubing connector to the tubing, and the tubing connector needle to the tubing connector.

iii. Nominal dimensions:

ID of tubing:	0.38 mm
OD of tubing:	1.5 mm
Tubing length:	23 in. (58 cm); 43 in. (109 cm)
Number of lumens:	One
Shape of lumen:	Round
Tip configuration:	PTFE catheter
ID of catheter:	0.39 mm
OD of catheter:	0.52 mm
Length of catheter:	16 mm
Tip of catheter:	Beveled 15 to 30 degrees
Introducer needle:	304 Stainless
ID of needle:	0.20 mm
OD of needle:	0.40 mm
Tip of needle:	A-Bevel
Proximal end configuration:	Proprietary Tubing Connector
Tubing connector needle:	26 gauge
ID:	0.010 in.
OD:	0.018 in.
Length:	0.230 in.
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

e. Mechanical specifications: The infusion set is designed and will be tested to (b)(4) [redacted]

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f. Biological specifications

i. ISO 10993 determination: The Paradigm Silhouette infusion set will meet ISO 10993 biocompatibility standards.

ii. Biocompatibility evaluations: The Paradigm Silhouette infusion set is made of many of the same materials as the predicate device which meets ISO 10993 standards for device biocompatibility.

g. Chemical specifications

i. Compatibility and stability requirements: The infusion set is intended to be used with insulin and any other medication suitable for infusion by an external pump. The compatibility and stability of (b)(4), the inner layer of tubing, has been well established through use with other infusion sets including (b)(4) Use of this material raises no new questions of chemical compatibility.

ii. DEHP: Since the new device contains no flexible PVC, it contains no DEHP plasticizer.

h. Product specification: The product specification is included in Appendix 1. A risk analysis is included in Appendix 7.

5. Labels, Labeling and Advertisements

a. Package labels: Copies of the sterile pack and box labels for the device are included in Appendix 3.

b. Instructions for Use: A copy of the device Instructions for Use is included in Appendix 4.

c. Promotional materials: No promotional material has been developed for this device at this time.

6. Photographs

Photographs of the device are include in Appendix 5.

7. Engineering Drawings

Engineering drawings are included in Appendix 6.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 51.

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8. Class III Summary

Not applicable. The device is not a Class III device.

9. Performance Standards

To the best of our knowledge and understanding, no performance standards have been established for devices of this type under section 514 of the Act. However, the device or components have been designed to conform to the following U.S. and international standards to the extent practicable:

U.S. Quality System Regulation; 21 CFR 820;

EN 46001: Quality Systems - Medical Devices - Particular requirements for the application of ISO 9001;

ISO 9001: Quality Systems: Model for quality assurance in design, development, production, installation and servicing;

93/42/EEC: Council Directive of 14 June 1993 concerning medical devices;

EN 550: Sterilization of medical devices - validation and routine control of ethylene oxide sterilization;

EN 556: Sterilization of medial devices - requirements for the devices to be labeled "Sterile";

ISO 10555: Sterile, single-use intravascular catheters;

ISO 10993-1: Biological evaluation of medical devices - Guidance on selection of tests;

ISO 10993-7: Biological evaluation of medical devices - Ethylene oxide sterilization residuals;

DIN 58362: Infusion equipment and accessories.

10. Performance Data

a. Bench data: A qualification test plan, which outlines testing that will be done, is included in Appendix 2.

b. Comparative claims: Any comparisons to other infusion sets will be limited to comparisons of product specifications.

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c. Unique designs: The design of the infusion set is a modification of the design of the predicate device. The tubing connector is a unique design of MiniMed Inc.

d. Biocompatibility data: The administration set materials will meet ISO 10993 specifications for biocompatibility.

e. Drug/device compatibility: The infusion set is intended to be used with insulin and any other medication suitable for infusion by an external pump. Drug device compatibility should not be expected to differ from the predicate device.

f. Drug stability: The stability of insulin for use with external infusion pump delivery systems is widely known and accepted. Insulin will be stored in a MiniMed subcomponent reservoir.

g. Residual volume: The residual volume will vary according to the length of the administration set tubing. With the 23 in. tubing, the residual volume is approximately 0.1 ml; with the 43 in. set, the residual volume is approximately 0.18 ml.

11. Sterilization Information

a. Sterilization method: (b)(4) [redacted]

b. Description of sterilization cycle validation method: Sterilization is accomplished according to the methods described in (b)(4) [redacted].

c. Sterility Assurance Level: The sterilization method for this device will result in a (b)(4) [redacted], producing a Sterility Assurance Level of 10 [redacted] according to (b)(4) [redacted].

d. Description of packaging to maintain sterility: The sets will come individually packaged in (b)(4) [redacted] packs with the clear tray portion manufactured from a rigid (b)(4) [redacted]. The (b)(4) [redacted] packs are sealed with (b)(4) [redacted]. The package can include one complete set (catheter and tubing) or a complete set and an additional stand-alone catheter. After packaging, the devices are boxed and sterilized. Full sets are sold in 10 sets per box. Combo sets contain 5 catheter only blister packs and 5 full tubing set packs per box.

e. ETO residues: The sterilant residual levels will comply with the requirements specified for prolonged exposure devices in (b)(4) [redacted]

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f. "Pyrogen Free" statement and method: The device will be non-pyrogenic on the basis of Material-mediated USP Pyrogen test conducted by Maersk Medical A/S at facilities in Denmark. The determination is based on the [redacted] test, completed in accordance with USP 23 *Bacterial Endotoxins Tests (85)* and validated according to the document "(b)(4) [redacted]

g. Sterilizer information: The new infusion set will be sterilized by Maersk Medical A/S, at sterilization facilities in Denmark:

Maersk Medical A/S
Unovej 1
DK-3390 Hundested
Denmark

12. Kit Certification Statement

Not applicable.

13. Guidance Document Issues

Development of this submission has relied, in part, on HHS Publication FDA 95-4158, "Premarket Notification 510(k): Regulatory Requirements for Medical Devices." This premarket notification was also prepared with reference to the guidance document "Guidance on Premarket Notification [510(k)] Submissions for Short and Long-Term Intravascular Catheters". Labeling was developed in accordance with FDA's Device Labeling Guidance, Memorandum G91-1, dated March 8, 1991.

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Section G. Description of the Lawfully Marketed Equivalent Device

1. Device Trade or Proprietary Name

Maersk Medical Pureline™ Comfort™ Subcutaneous Infusion Set (hereinafter, Comfort Set). This was originally submitted as the Pharma-Plast Pureline™ Comfort™ infusion set. This set is marketed by MiniMed Inc. as the Silhouette® infusion set.

2. Device Common and Classification Name(s)

Common Name:	Subcutaneous Infusion Administration Set
Classification Name:	Intravascular Administration Set Fluid Delivery Tubing

3. Device Classification Information

Class:	II
Panel:	80
Product Code:	FPA
Cite:	21 CFR 880.5440

4. Document Control Number(s)

K972135

5. Description of the Marketed Equivalent Device

a. Type of device: The new device, the Paradigm Silhouette infusion set is substantially similar to the Maersk Comfort Set, the lawfully marketed equivalent device. The predicate device is a subcutaneous infusion set, used for administering fluids subcutaneously from an infusion pump or by injection. The device consists of an indwelling catheter inserted by means of a stainless steel insertion needle. This catheter is attached externally by a hub, affixed by an adhesive tape to the skin of the device user. Fluid is delivered through a length of tubing which is attached to an external infusion pump or syringe reservoir via a standard Luer connection. The tubing may be disconnected from the indwelling catheter for temporary interruptions of pump use, or to use the set as an access port for subcutaneous delivery of fluids or medications.

b. Use with other devices: The predicate device is designed for use with syringe reservoirs with a standard Luer connector.

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c. Physical specifications

i. Components and materials: Following is a list of the principal components of the Comfort infusion set:

Part Description	Material
Needle protector	(b)(4) [redacted]
Introducer needle	
Catheter	
Fixation tape	
Cannula housing	
Introducer needle hub	
Teflon bush	
Injection port	
Segment	
Connector needle	
Connector hub	
Tubing	
Adhesive	
Luer lock	
Cap	

ii. Nominal dimensions:

ID of tubing:	0.38 mm
OD of tubing:	1.5 mm
Tubing length:	23 in. (60 cm); 31 in. (80 cm); 43 in. (110 cm)
Number of lumens:	One
Shape of lumen:	Round
Tip configuration:	PTFE catheter
ID of catheter:	0.39 mm
OD of catheter:	0.52 mm
Length of catheter:	16 mm
Tip of catheter:	Beveled 15 to 30 degrees
ID of needle:	0.20 mm
OD of needle:	0.40 mm
Tip of needle:	A-Bevel
Proximal end configuration:	Luer connector
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

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d. Mechanical specifications: Each catheter is designed and will be tested to

(b)(4) [redacted]

e. Biological specifications: The administration set materials meet ISO 10993 specifications for biocompatibility.

f. Chemical specifications

i. Compatibility and stability requirements: The infusion set is intended to be used with insulin and any other fluids, solutions, or medications suitable for infusion by an external pump. The compatibility and stability of (b)(4) [redacted] the inner layer of the tubing, has been well-established through use with other infusion sets.

ii. DEHP: Since the predicate device contains no flexible PVC, it contains no DEHP plasticizer.

6. Intended Use of the Marketed Equivalent Device

The Maersk Medical Comfort infusion set is intended for infusing or injecting fluids into the body subcutaneously. The indwelling catheter can be inserted independently of the infusion catheter and accessed for injections through an injection port. The infusion set can be temporarily detached from the indwelling catheter.

7. Labels and Labeling

Sterile pack and box labels of the predicate device are included in Appendix 8. A copy of the predicate device Instructions for Use is included in Appendix 9.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section H. Comparison of the New and Existing Devices

1. Similarities

The Paradigm Silhouette infusion set is a modified version of the Maersk Comfort infusion set. Both the new and the predicate infusion sets are used for subcutaneous delivery of insulin or other appropriately labeled medicines from an infusion pump to the pump user. Both sets attach proximally to a reservoir and insert distally to the user with a removable stainless steel needle and flexible catheter made of PTFE.

The length of tubing, hub, adhesive dressing, needle and catheter of the two sets are identical.

The intended use of the two devices is substantially similar:

> **Predicate:** The Comfort infusion set is intended for infusion/injection of fluids into the body below the surface of the skin. The indwelling catheter can be inserted independently from the infusion catheter and can be accessed for injections through the injection port. The indwelling catheter can also be securely attached to the infusion catheter by means of the proprietary "click-lock" connector for the infusion of drugs subcutaneously. The infusion set can be detached from the indwelling catheter, and the catheter capped, to allow freedom from the infusion pump for showers, athletics or other activities (quoted from the premarket notification, page 5).
>
> **New Device:** The Paradigm Silhouette infusion set is intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

2. Differences

(b)(4)

[redacted]

3. Effect of Changes on Safety and Effectiveness

The modification which is the subject of this premarket notification has no untoward effect on the safety and effectiveness of the device. The change does not affect the basic characteristics of the device nor the intended use of the device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Table of Comparison

FEATURES:	Comfort (Marketed Device)	Paradigm Silhouette (New Device)
Tubing	Polyethylene/ Polyurethane	Polyethylene/ Polyurethane
Length	60, 80, 110 cm	58, 109 cm
Connector	Female Luer	Tubing Connector
Introducer needle material	304 Stainless	304 Stainless
Introducer needle gauge	27 gauge	27 gauge
Introducer needle removable	Yes	Yes
Insertion angle	30 degrees	30 degrees
Indwelling catheter material	PTFE	PTFE
Indwelling catheter gauge	25 gauge	25 gauge
Indwelling catheter length	16 mm	16 mm
Disconnect feature	Yes	Yes
Dead Space needle	0.0075 ml	0.0075 ml
Volume per set	0.1 - 0.18 ml	0.1 - 0.18 ml
Insertion duration hours	Up to 72 hours	Up to 72
Intended Use	Subcutaneous infusion of medicine, including insulin, from an infusion pump or use as an injection port.	Subcutaneous infusion of medicine, including insulin, from a MiniMed Paradigm infusion pump.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 59

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Section I. Appendices

1. Product Specification: Paradigm Silhouette Infusion Set
2. Qualification Plan: Paradigm Silhouette Infusion Set
3. Sterile Pack and Box Labels: Paradigm Silhouette Infusion Set
4. Instructions for Use: Paradigm Silhouette Infusion Set
5. Photographs: Paradigm Silhouette Infusion Set
6. Engineering Drawings: Paradigm Silhouette Infusion Set
7. Risk Analysis: Paradigm Silhouette Infusion Set
8. Sterile Pack and Box Labels: Comfort Infusion Set
9. Instruction for Use: Comfort Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 1. Product Specification: Paradigm Silhouette Infusion Set

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Product Specification: Paradigm Silhouette

ID of tubing:	0.38 mm
OD of tubing:	1.5 mm
Tubing length:	23 in. (58 cm); 43 in. (109 cm)
Number of lumens:	One
Shape of lumen:	Round
Tip configuration:	PTFE catheter
ID of catheter:	0.39 mm
OD of catheter:	0.52 mm
Length of catheter:	16 mm
Tip of catheter:	Beveled 15 to 30 degrees
Introducer needle:	304 Stainless
ID of needle:	0.20 mm
OD of needle:	0.40 mm
Tip of needle:	A-Bevel
Proximal end configuration:	Proprietary Tubing
Connector Tubing connector needle:	26 gauge
ID:	0.010 in.
OD:	0.018 in.
Length:	0.230 in.
Tubing composition:	Polyurethane (outer); Polyethylene (inner)

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Appendix 2. Qualification Plan: Paradigm Silhouette Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Qualification Test Plan for (b)(4) [redacted] - English version

Summary of tests.

General:

All test will be conducted after 2 x sterilisation

No.	Ref. to risk-analyse Product-parametre	QTP no.	Test	Method	Approval	Completed Date + Init.
1	(b)(4) [redacted]					
2						
3						

Udarbejdet af: (b)(6) [redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 3. Sterile Pack and Box Labels: Paradigm Silhouette Infusion Set

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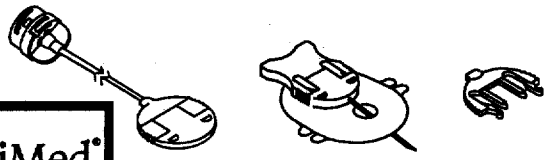
paradigm

Silhouette® INFUSION SET



(1x) 43" (109 cm) (1x) (1x)

Made for:

MiniMed®

USA:
Sylmar, CA
818-362-5958 • 800-843-6687

EUROPE:
DARTEC AB, Hällviken, Sweden
(46) 40 45 92 50

Made in Denmark by:
Maersk Medical A/S, DK-4000

CAUTION: U.S. law restricts this device to sale by, or on the order of a physician.

U.S.Patent No. 5,522,803

REF MMT-377

CE 0301

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D6024695-001 6/00

Sheet 1 of 1
DMP6024695-001 Rev A

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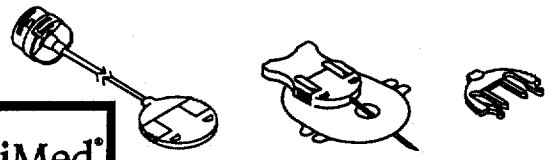
paradigm

Silhouette® INFUSION SET



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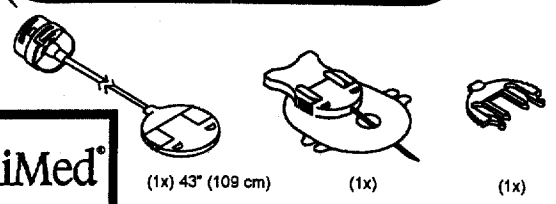
Silhouette® INFUSION SET



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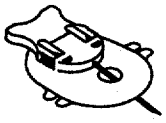
Silhouette® INFUSION SET



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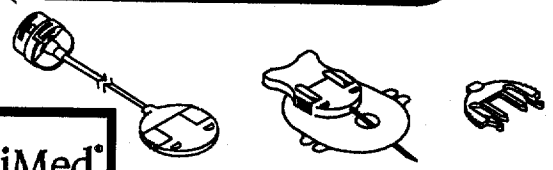
Silhouette® INFUSION SET



(1x) 23" (58 cm) (1x) (1x)

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REF MMT-380A

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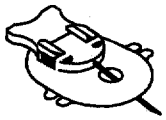
Silhouette® INFUSION SET



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(46) 40 45 92 50

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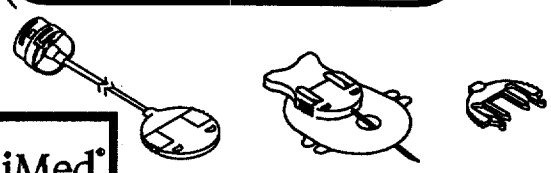
Silhouette® INFUSION SET



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(46) 40 45 92 50

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U.S.Patent No. 5,522,803

REF MMT-377

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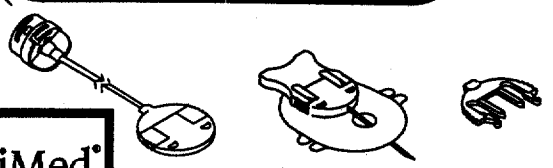
Silhouette® INFUSION SET



(10x) 23" (58 cm) (10x) (10x)

Made for:

MiniMed®

USA:
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818-362-5958 • 800-843-6687

EUROPE:
DARTEC AB, Höllviken, Sweden
(46) 40 45 92 50

Made in Denmark by:
Maersk Medical A/S, DK-4000

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U.S.Patent No. 5,522,803

REF MMT-378

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D6024700-001 6/00

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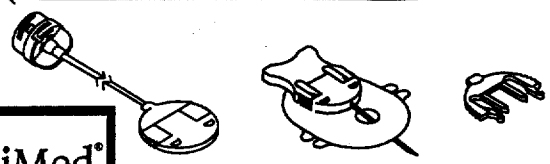
Silhouette® INFUSION SET



(5x) 43" (109 cm) (10x) (5x)

Made for:

MiniMed®

USA:
Sylmar, CA
818-362-5958 • 800-843-6687

EUROPE:
DARTEC AB, Hölviken, Sweden
(46) 40 45 92 50

Made in Denmark by:
Maersk Medical A/S, DK-4000

CAUTION: U.S. law restricts this device to sale by, or on the order of a physician.

U.S.Patent No. 5,522,803

REF MMT-379 Combo

LOT

CE 0301

D6024701-001 6/00

STERILE EO

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DMP 6024701-001 Rev A
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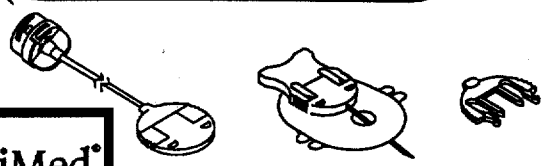
Silhouette® INFUSION SET



(5x) 23" (58 cm) (10x) (5x)

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MiniMed®

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818-362-5958 • 800-843-6687

EUROPE:
DARTEC AB, Hällviken, Sweden
(46) 40 45 92 50

Made in Denmark by:
Maersk Medical A/S, DK-4000

CAUTION: U.S. law restricts this device to sale by, or on the order of a physician.

U.S.Patent No. 5,522,803

REF MMT-380 Combo

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DMP6024702-001 Rev A
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Appendix 4. Instructions for Use: Paradigm Silhouette Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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USE FILE FOR VENDOR

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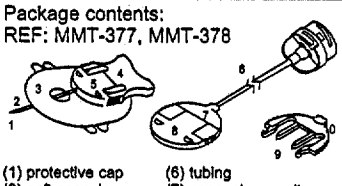
Silhouette® INFUSION SET

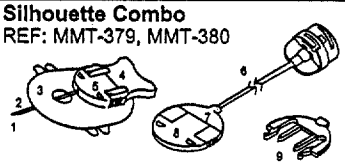
Instructions for Use

Package contents:
REF: MMT-377, MMT-378



(1) protective cap
(2) soft cannula (25G x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing
(6) tubing
(7) connector needle
(8) circular protective cap
(9) disconnect cover
(10) tubing connector

Silhouette Combo
REF: MMT-379, MMT-380



Package A contents:
(1) protective cap
(2) soft cannula (25G x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing
(6) tubing
(7) connector needle
(8) circular protective cap
(9) disconnect cover
(10) tubing connector

Package B contents:
(1) protective cap
(2) soft cannula (25G x 17 mm)
(3) adhesive tape
(4) introducer needle
(5) cannula housing

Remark: This version allows you to change the soft cannulas twice for every tubing used. For the first time, use a soft cannula and a tubing (see above package A).

STERILE DEVICE
This device is sterile unless the package has been opened or damaged. Do not use if the sterile package has been opened or damaged.

PRECAUTIONS
- Read instructions for use carefully before handling Paradigm Silhouette.
- If using Paradigm Silhouette for the first time, do your first set up in the presence of your healthcare professional.
- If using insulin, check blood glucose 1 to 3 hours after insertion and re-check blood glucose levels frequently during the day according to your healthcare professional's recommendation.
- The numbers in the text refer to the package contents diagram.

INDICATIONS FOR USE
The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump.

CONTRAINDICATIONS
The Paradigm Silhouette infusion sets are contraindicated for the infusion of blood.

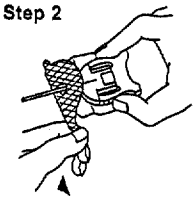
ADVERSE REACTIONS
Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of an infusion site. Users are advised to review carefully the directions for inserting and securing the infusion set.

INSERTING THE PARADIGM SILHOUETTE

Step 1

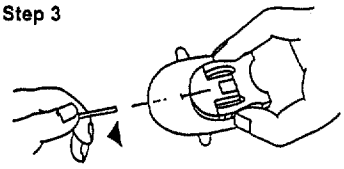
Prepare the skin at the infusion site. Select a site away from the belt line to keep the soft cannula from getting dislodged and to prevent irritation. The injection site should be cleaned thoroughly and allowed to dry before the Paradigm Silhouette is inserted.

Step 2



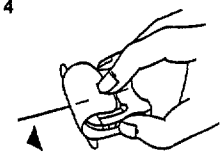
Remove the front half of the backing paper from the white adhesive tape(3).

Step 3



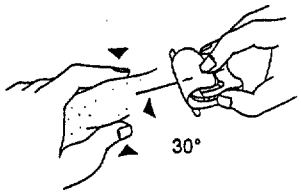
Remove the plastic protective cap (1) from the needle.

Step 4



Hold the Paradigm Silhouette as shown in the Figure above, using the index finger to hold back the forward flap of the white adhesive tape (3).

Step 5



With the other hand, pinch the subcutaneous tissue as you would to give an injection. Push the needle with a firm motion into the infusion site at a 30 degree angle.

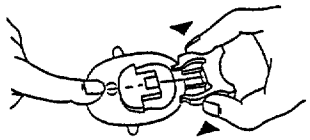
Important: People with small or large amounts of subcutaneous fat should be careful when choosing the insertion angle because the cannula could be placed in the underlying muscle layer or in the dermal layer and therefore cause reduced or blocked medication delivery (check with your healthcare professional regarding this point).

Make sure that the soft cannula is well inserted into the subcutaneous tissue.

Step 6

Carefully smooth out the front half of the adhesive tape (3) onto the skin.

Step 7

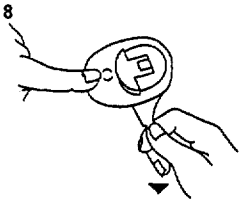


To remove the introducer needle (4), put one finger just in front of the see-through window to keep Paradigm Silhouette in place and with your other hand, press gently the side clips with two fingers while simultaneously withdrawing the introducer needle.

Note: The introducer needle (4) goes through a clear tube, called the soft cannula (2) which is what remains in the subcutaneous layer after the introducer needle is removed.

Remark: Dispose of the introducer needle (4) in a safe manner in a sharps container.

Step 8



Remove the back side of the backing paper and smooth out the white adhesive tape (3) to make sure good skin contact is achieved.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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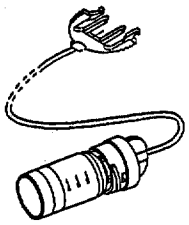
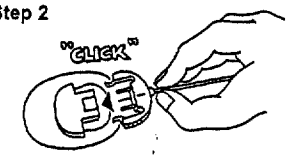
CONNECTING THE PARADIGM SILHOUETTE

Step 1



Attach the tubing connector (10) to the reservoir and pump according to the Paradigm pump User's Guide. Remove the circular protective cap (8) at the end of the tubing by gently pressing the side clips of the connector needle (7). Follow the Paradigm pump User's Guide to prime the set. Prime the tubing (6) until medication drips from the connector needle (7).

Step 2



Hold the connector needle (7) with the rounded side facing up and insert it into the cannula housing (5) until you hear an audible "click".

Important: Give a slight pull on the tubing (6) to check if the two parts are well connected.

Remark: Keep the circular protective cap (8) and the disconnect cover (9) in the individual blister pack (click the two pieces together). You will need these pieces if you intend to disconnect.

PRECAUTIONS

It is generally advisable to administer a bolus of at least 0.0075 ml (for insulin: 0.5-1 unit of U-100) to fill the empty space in the soft cannula after the introducer needle is withdrawn. Follow the recommendation of your healthcare professional.

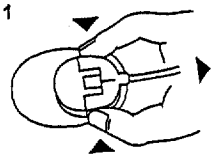
DISCONNECTING THE PARADIGM SILHOUETTE

The Paradigm Silhouette allows you the freedom to temporarily disconnect from your pump for showers, swimming etc., without changing your infusion set.

PRECAUTION

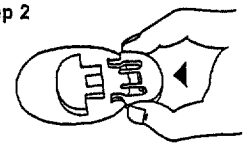
Please consult with your healthcare professional on how you should compensate for any missed medication when you are disconnected. If using insulin, carefully monitor blood glucose levels when you are disconnected from the pump and after you re-connect to the pump.

Step 1



Remove the tubing (6) by gently pressing the side clips of the connector needle (7) as shown. Use the circular protective cap (8) to protect the connector needle (7).

Step 2



Insert the disconnect cover (9) into the cannula housing (6) until you hear an audible "click".

Important:
Before re-connecting, ensure that a drop of insulin or medication appears at the tip of the connector needle (see step 2 - Connecting the Paradigm Silhouette).

SYMBOL	MEANING
	EXPIRATION DATE
	DO NOT RE-USE
	READ INSTRUCTIONS FOR USE
LOT	LOT NUMBER
STERILE EO	STERILIZED WITH ETHYLENE OXIDE
REF	REFERENCE/MODEL NUMBER
	OPEN HERE

WARNINGS

- A small percentage of soft cannula sets may crimp upon insertion or become dislodged during use.
- Do not leave air in infusion set. Prime completely.
- Use aseptic techniques when temporarily disconnecting the set. Be certain to cap the tubing and the cannula housing with the cover provided.
- Replace the Paradigm Silhouette if the dressing tape comes loose, because the soft cannula may be half way out or dislodged.
- If the infusion site becomes inflamed, replace the set and use a new site until the first site has healed.
- Do not put disinfectants, perfumes, or deodorants on your infusion set as these may affect the integrity of the set.
- **Never prime the set or attempt to free a clogged line while the infusion set is inserted. You may accidentally inject too much medication.**
- Do not reinsert the introducer needle into the infusion set. Re-insertion could cause tearing of the soft cannula which would result in unpredictable medication flow.
- Replace the infusion set according to CDC (Centers for Disease Control) guidelines (every 72 hours) or institutional protocol.
- For subcutaneous use only, not for IV (intravenous) infusion.
- Dispose of properly after single use. Do not clean or re-sterilize.
- CAUTION: U.S. law restricts this device to sale by or on the order of a physician.

If you are using insulin:

- Check frequently to make sure the soft cannula remains firmly in place. Because the cannula is so soft, you will not notice any pain if it pulls out. The soft cannula must always be completely inserted so that you receive the full amount of medication.
- Check blood glucose level 1 to 3 hours after inserting a Paradigm Silhouette and monitor the infusion site by using the see-through window integrated in the white dressing tape. Check blood glucose frequently (check with your physician).
- Do not insert a new soft cannula just prior to bedtime unless blood glucose can be checked 1-3 hours after insertion.
- If your blood glucose level becomes unexplainably high or an occlusion alarm occurs, check for clogs and leaks. If in doubt, change infusion set; the soft cannula could be dislodged or partially clogged.
  - Check blood glucose one hour after changing Paradigm Silhouette and test again more often to make sure you have corrected the problem.
  - If still high, contact your physician immediately.
  - If your physician is not available, inject insulin manually per your physician's recommendation.
- Preventing hyperglycemia - Prevention is your responsibility. Therefore, discuss with your physician a plan of action for rapid replacement of insulin should your soft cannula become dislodged.

Made for:

MiniMed®

USA:
Sylmar, CA
818-362-5958 • 800-826-2099 (24-hour Help Line within U.S. & Canada)
818-678-5555 (outside U.S.)

To order supplies:
800-843-6687 • Fax: 888-268-0200 (within U.S. & Canada)
Fax: 818-362-3788 (outside U.S.)

Made in Denmark by: Maersk Medical A/S, DK-4000

These products are covered by one or more of the following U.S. or foreign patents: [U.S.] 5,522,803 Other U.S. and/or foreign patents may be pending.

Silhouette is a registered trademark of MiniMed Inc.
Paradigm is a trademark of MiniMed Inc.

D9195851-011 3/00 0301 CE

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 5. Photographs: Paradigm Silhouette Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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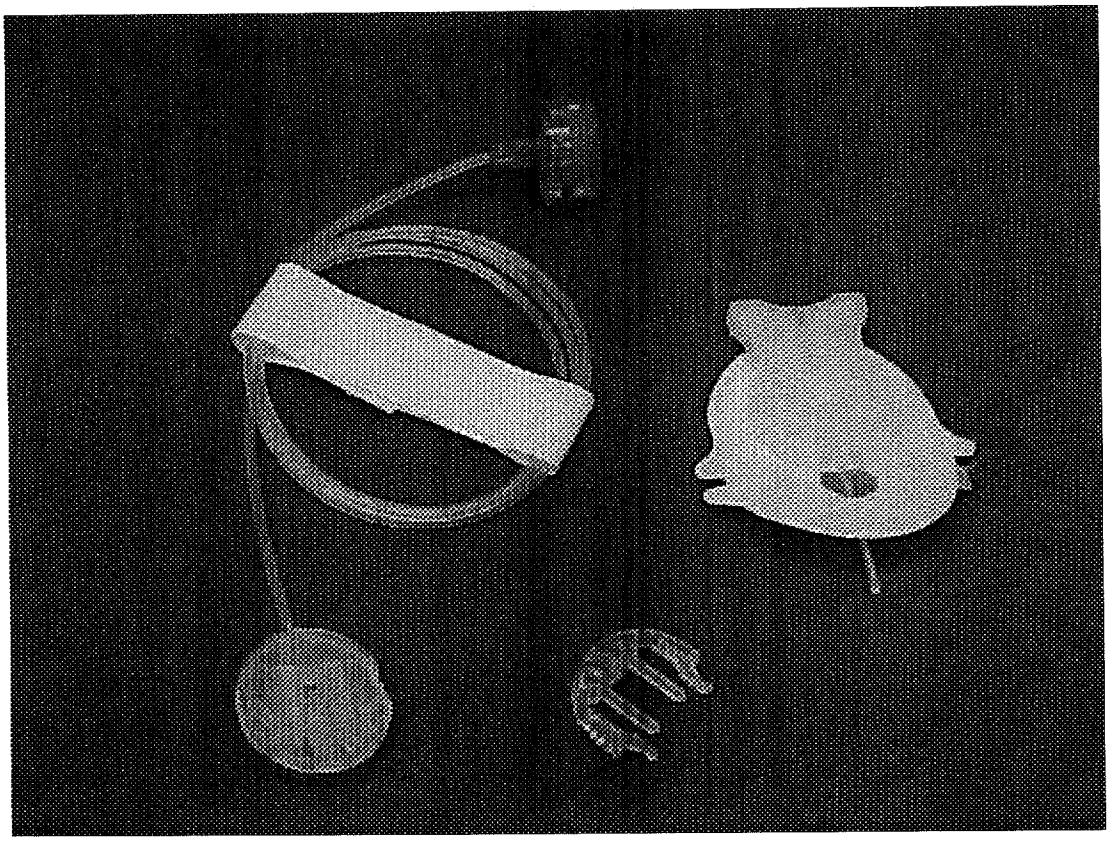

Figure 1. Paradigm Silhouette Infusion Set

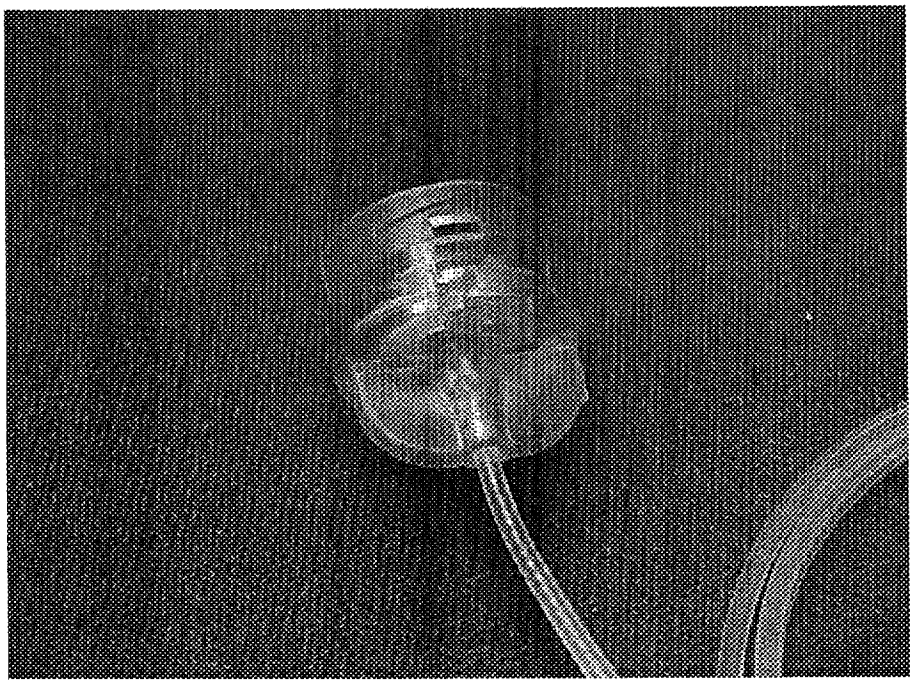

Figure 2. MiniMed Tubing Connector

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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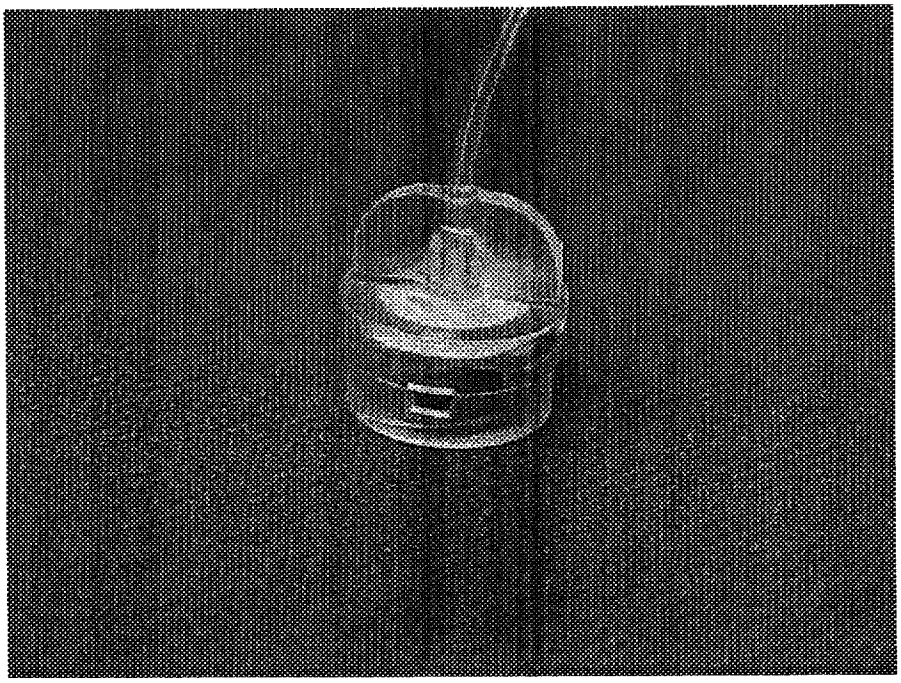

Figure 3. MiniMed Tubing Connector Side View

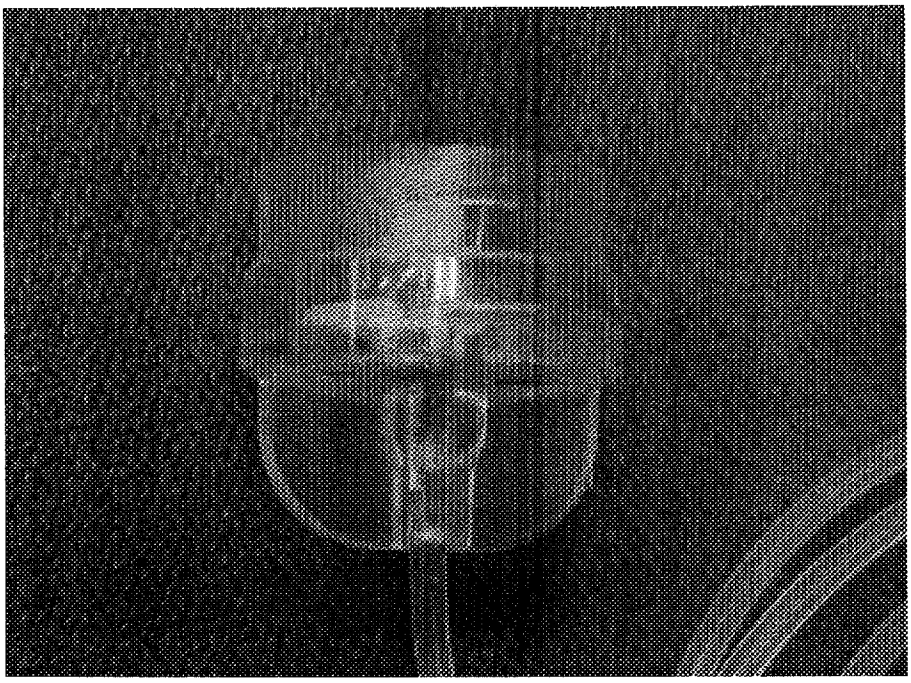

Figure 4. MiniMed Tubing Connector Side View

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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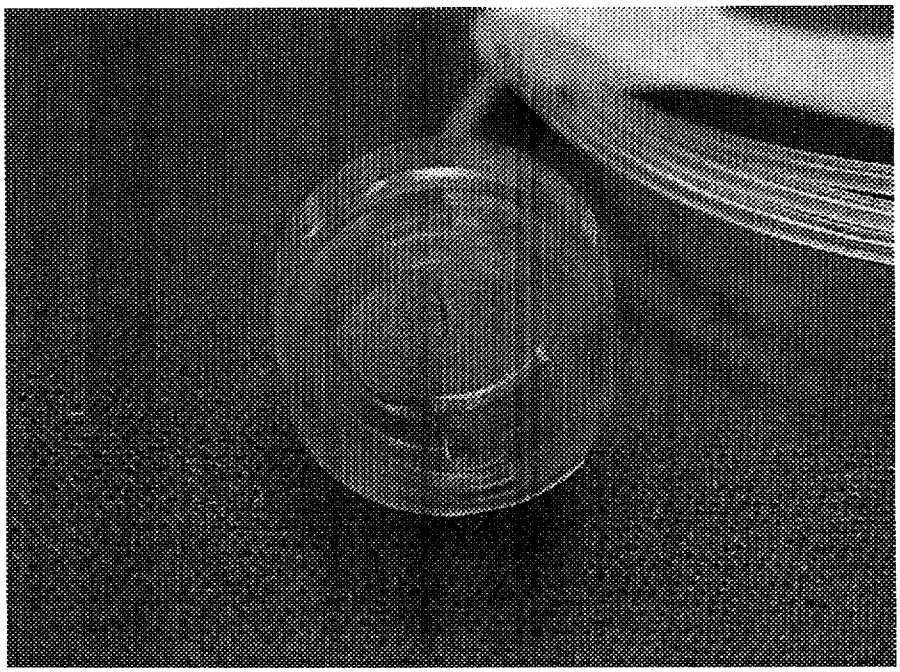

Figure 5. MiniMed Tubing Connector Needle for Fluid Path

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 6. Engineering Drawings: Paradigm Silhouette Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Engineering Drawings

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Appendix 7. Risk Analysis: Paradigm Silhouette Infusion Set

A plan for implementation of the activities to mitigate the hazards are listed in the risk analysis document.

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Risk Analysis-english version

(b)(4) [redacted]

Number of revisio: (b)(4) [redacted]

Made by: (b)(6) [redacted]

Date: 06-12-99

Number of project:

Project manager: (b)(6) [redacted]

Working group: validation group

Sign. (QA manager) (b)(6) [redacted]

Date: 24/2-2000

Reference: Document (b)(4) [redacted] (Riskanalysis)

Uncontrolled copy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

(b)(4) Risk Analysis

Records processed under FOIA Request # 2015-5906; Released by CDRH on 11-10-2015

[redacted]

(b)(4) Risk Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

(b)(4) Risk Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 8. Sterile Pack and Box Labels: Comfort Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 90

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Pureline

Comfort

Single Use Insulin Infusion Set With Teflon Cannula:
Sterilized by ethylenoxid, sterile unless package is opened or damaged. Non toxic,non pyrogenic. Insulin compatible.

WARNING: A small percentage of Comfort sets may 'buckle' upon insertion or become dislodged during use. Such conditions may be difficult to detect.
READ INSTRUCTION BEFORE USING THE PRODUCT.
CAUTION : Federal law restricts this device to sale by, or on the order of a physician

Needle	25G (0,5 mm) x 17 mm
Tubing length:	31 inch.
Deadspace:	0,13 ml
Product No.:	89 080 2622
Batch No.:	500500
Use before:	2002-09

CHRONIMED
800-888-5957

Made in Denmark US patent No. 5,522,803

Single Use Insulin Infusion Set With Teflon Cannula :
Sterilized by ethylenoxid, sterile unless package is opened or damaged. Non toxic, non pyrogenic. Insulin compatible.
Warning: A small percentage of Comfort sets may "buckle " upon insertion or become dislodged during use. Such conditions may be difficult to detect
READ INSTRUCTION BEFORE USING THE PRODUCT:
CAUTION: Federal law restricts this devise to sale by, or on the order of a physician.

Needle:	25g (0.5 mm) x 17 mm
Tubing length:	31 inch.
Deadspace:	0.13 ml
Product No:	89-080 -2622
Batch No:	500500
Use before:	2002-09
Made in Denmark	US patent No. 5 522.803

CHRONIMED
800-888-5957
10 pcs.

"Carefully read directions for use located in bottom slot .
Distributed by Chronimed Inc. Phone 800-848-0614"

Single Use Insulin Infusion Set With Teflon Cannula:
Sterilized by ethylenoxid, sterile unless package is opened or damaged. Non toxic,non pyrogenic. Insulin compatible.
Warning: A small percentage of Comfort sets may "buckle " upon insertion or become dislodged during use. Such conditions may be difficult to detect
READ INSTRUCTION BEFORE USING THE PRODUCT.
CAUTION: Federal law restricts this device to sale by, or on the order of a physician.

Needle:	25G (0.5 mm) x 17 mm
Tubing length:	31 inch.
Deadspace:	0.13 ml
Product No:	89-080-2622
Batch No:	500500
Use before:	2002-09
Made in Denmark	US patent No. 5,522,803

CHRONIMED
800-888-5957
200 pcs.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Appendix 9. Instruction for Use: Comfort Infusion Set

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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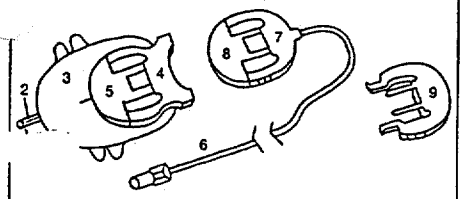
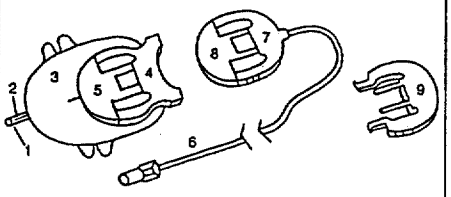
Comfort hospital Package contents:



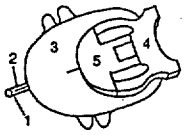
(1) protective cap
(2) soft cannula
(3) adhesive tape
(4) introducer needle
(5) cannula housing
(6) tubing
(7) connector needle
(8) circular protective cap
(9) disconnect cover

Comfort Package 1 contents:



(1) protective cap
(2) soft cannula
) adhesive tape
) introducer needle
(5) cannula housing
(6) tubing
(7) connector needle
(8) circular protective cap
(9) disconnect cover

Package 2 contents:



(1) protective cap
(2) soft cannula
(3) adhesive tape
(4) introducer needle
(5) cannula housing

Remark: This version allows you to change the soft cannulas twice for every tubing used. For the first time, use a soft cannula and a tubing (see above package 1).

Important: Change soft cannula or tubing at least every 2-3 days (max. 72 hours).

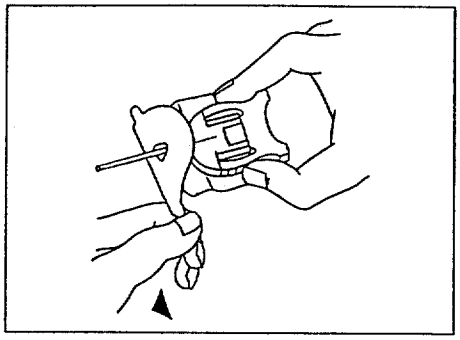
Precautions

- **First time use, set up should be done in the presence of a health care professional.**
- **Instructions for use should be read carefully before use.**

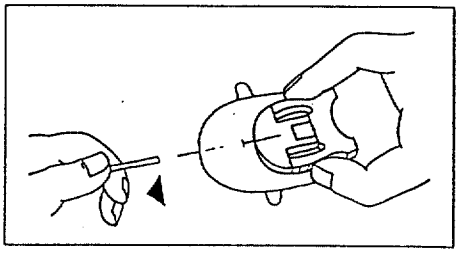
Inserting Comfort

Step 1 Prepare the skin at the infusion site (the abdomen is the most commonly chosen site). Select a site away from the belt line to keep the soft cannula from getting dislodged and to prevent irritation. The injection site should be cleaned thoroughly and allowed to dry before the Comfort is inserted.

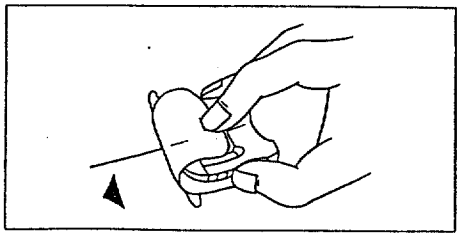
Step 2 Remove the front half of the backing paper from the white adhesive tape.



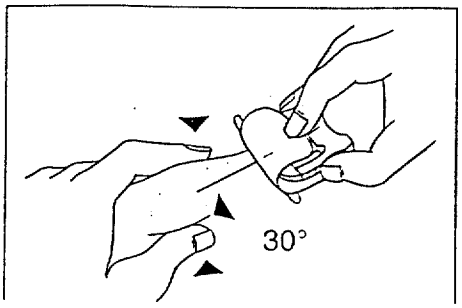
Step 3 Remove the plastic protection cover from the needle.



Step 4 Hold the Comfort as shown in the Figure below, using the index finger to keep the forward flap of the white adhesive back (3).



Step 5 With the other hand, pinch the subcutaneous tissue as you would to give an injection. Push the needle with a firm motion into the infusion site at a 30 degree angle.

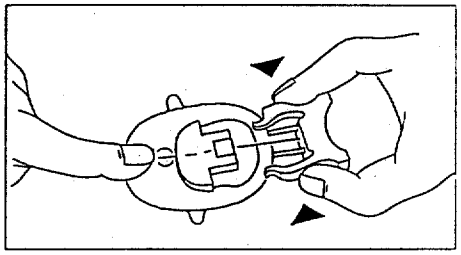


should be careful when choosing the insertion angle because the cannula could be placed in the underlying muscle layer or in the dermal layer and therefore cause reduced or blocked medication delivery (check with your health care professional regarding this point).

Make sure that the soft cannula is well inserted into the subcutaneous tissue.

Step 6 Carefully smooth out the front half of the backing paper onto the skin.

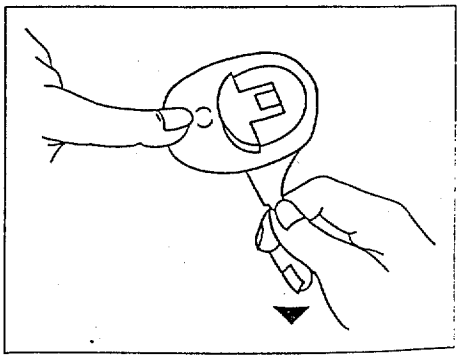
Step 7 To remove the introducer needle, put one finger just in front of the see-through window to keep Comfort in place and with your other hand, press gently the side clips with two fingers while simultaneously withdrawing the introducer needle.



Note: The introducer needle goes through a clear tube, called the soft cannula which is what remains in the subcutaneous layer after the introducer needle is removed.

Remark: Remember to dispose of the introducer needle in a safe manner (needle container).

Step 8 Remove the back side of the backing paper and smooth out the white adhesive tape to make sure good skin contact is achieved.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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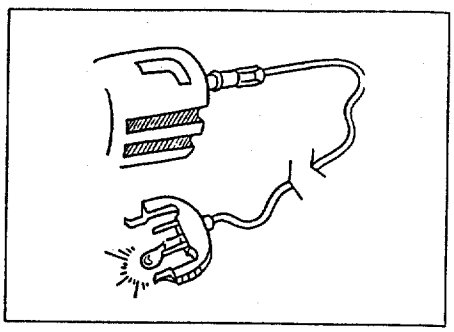
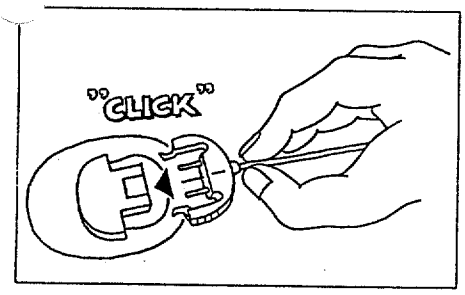
Step 1 Attach the tubing (6) to the pump. Remove the circular protection cap (8) at the end of the tubing by gently pressing the side clips of the connector needle (7). Follow the pump manufacturers instructions for use for priming. Prime the tube until medication drips from the connector needle (7).



Note: Number of units of U-100 insulin needed to prime the tubing:

23" (60cm) : approx. 10 units
31" (80 cm): approx. 13 units
43" (110 cm): approx. 18 units

Step 2 Hold the connector needle (7) with the rounded side facing up and insert it into the cannula housing (5) until you hear an audible "click".



Important: Give a slight pull on the tubing to check if the two parts are well connected.

Remark: Keep the circular protection cap (8) and the disconnect cover (9) in the individual blister pack (click the two pieces together). You will need these pieces if you intend to disconnect.

Precautions:

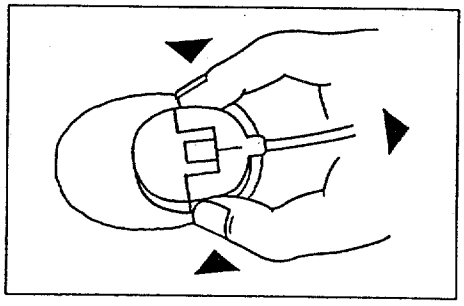
It is generally advisable to administer a bolus of at least 0.0075 cc (for insulin: approx. 1 unit of U-100) to fill the empty space in the cannula after the introducer edle is withdrawn. Check with your ealth care professional regarding use of this procedure.
Check blood glucose level 1 to 3 hours after inserting the Comfort. Monitor the infusion site by using the see-through window in the white dressing tape. Check blood glucose frequently (check with

Comfort allows you the freedom to temporarily disconnect from your pump for showers, swimming etc., without changing your infusion set.

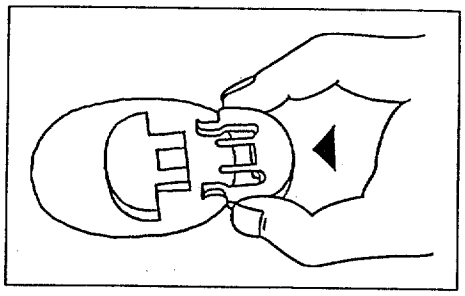
Precaution:

Please consult with your health care professional on how you should compensate for any missed insulin or medication when you are disconnected. Carefully monitor blood glucose levels when you are disconnected from the pump and after you re-connect to the pump.

Step 1 Remove the tubing by gently pressing the side clips of the connector needle (7) as shown. Use the circular protection cap (8) to protect the connector needle (7).



Step 2 Insert the disconnect cover (9) into the cannula housing (6) until you hear an audible "click".



Remark: To give insulin injections simply insert syringe or pen needle into the opening of the disconnect cover (9). Push the needle through the rubber membrane to ensure that insulin can be injected through the soft cannula.
Do not use a needle larger than a 27 gauge and longer than 1/2 an inch (12-13 mm).

Important: Before re-connecting, ensure that a drop of insulin or medication appears at the tip of the connector needle (see step 2 - Connecting Comfort).

- A small percentage of soft cannula sets may crimp upon insertion or become dislodged during use.
- Check blood glucose level 1 to 3 hours after inserting a Comfort and monitor the infusion site by using the see-through window integrated in the white dressing tape. Check blood glucose frequently (check with your physician).
- Check frequently to make sure the soft cannula remains firmly in place. Because the cannula is so soft, you will not notice any pain if it pulls ou soft cannula must always be completely inse so that you receive the full amount of insulin.
- Do not leave air in infusion set. Prime completely.
- Use aseptic techniques when temporarily disconnecting the set. Be certain to cap the tubing and the cannula housing with the cover provided.
- Replace the Comfort if the dressing tape comes loose, because the soft cannula may be half way out or dislodged.
- Do not insert a new soft cannula just prior to bedtime, unless blood glucose can be checked 1-3 hours after insertion.
- Never use a soft cannula or a tubing for more than 72 hours.
- If the infusion site becomes inflamed, replace the set and use a new site until the first site has healed.
- Do not put disinfectants, perfumes, or deodorants on your infusion set as these may affect the integrity of the set.
- Never prime the set or attempt to free a clogged line while the infusion set is inserted. You may accidentally inject too much insulin or medication.
- Do not reinsert the introducer needle into the infusion set. Reinsertion could cause tearing of the soft cannula which would result in unpredicte medication flow.
- If your blood glucose level becomes unexplainably high, or an "occlusion" alarm occurs, check for clogs and leaks. If in doubt, **change infusion set**: the soft cannula could be dislodged or partially clogged.

  * Check blood glucose one hour after changing Comfort and test again more often to make sure you have corrected the problem.

  * If still high, **contact your physician immediately.**

  * If your physician is not available, inject insulin manually as defined by your physician.
- Preventing hyperglycaemia - Prevention is your responsibility. Therefore, discuss with your physician a plan of action for rapid replacement of insulin should your soft cannula become dislodged.
- Replace the soft cannula according to CDC (Center for Disease Control) guidelines or institutional protocol.
- For subcutaneous use only, not for IV infusion.
- Destroy after single use. Do not clean or re-sterilize.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

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