K061374

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8.0 510(K) SUMMARY
Date Prepared: May 1, 2006

8.1 SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

John M. Lindskog
General Manager
Unomedical A/S
Infusion Devices
Aaholmvej 1-3, Osted
DK-4000 Roskilde, Denmark

JUL 31 2006

8.2	Trade/Proprietary Name:	Intuition Infusion Sets
8.3	Common/Usual Name	Subcutaneous catheter Insertion and Infusion Set
8.4	Classification Name	Intravascular Administration Set; Introducer, syringe needle
8.5	Classification	Class: II Panel: 80 Product Code: FPA; KZH Cite: 21 CFR 880.5440; 880.6920

8.6 Substantial Equivalence
The Intuition™ sets are substantially equivalent to the Paradigm Quick Set Infusion set (K011071), the Unomedical Pureline Comfort Subcutaneous Infusion Set (K972135), the Unomedical Inset™ Subcutaneous Infusion Sets (K032854) and the MiniMed Sil-serter™ (K010377).

8.7 Technological Characteristics
The Intuition™ Subcutaneous Infusion Sets have the same technological characteristics of the current marketed products.

8.8 Performance Data
Verification testing confirmed the product meets their specifications.

8.9 Conclusion
Unomedical A/S concludes based on the information presented that the new products lines are substantially equivalent to products currently legally marketed in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 2006

Mr. John M. Lindskog
General Manager
Unomedical A/S
Infusion Devices
AAholmvej 1-3, Osted
Roskilde, Denmark 4000

Re: K061374
Trade/Device Name: INTUITION Subcutaneous Catheter Insertion and Infusion Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: May 1, 2006
Received: May 17, 2006

Dear Mr. Lindskog:

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

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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number:

Device Name: INTUITION Subcutaneous Catheter Inserter and Infusion Set

Indications For Use: These sets are indicated for the infusion of fluids into the body below the surface of the skin when attached to a fluid reservoir.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature] 7/31/06

...n Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...Number K061374