JUL 2 3 2002

1C012720

510(k) SUMMARY
as required per 807.92(c)

1. Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: August 15, 2001

2. Trade Name, Common Name and Classification Name:

A. Trade Name:

INFINITY MICRO2+

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Oximeter	74 DQA	II	870.2700
Ear Oximeter	74 DPZ	II	870.2710

3. Predicate Device Identification:

MICRO2 510(k) K913489
SC 7000/9000XL K980882

Other Relevant Submissions

SC 9000	K946306
SC 9000 Neonatal	K962291
SC3000 WorkStation & Remote Display (MultiView WorkStation & Network)	K955059
MVWS INFINITY Telemetry System	K972714

4. Device Description:
The INFINITY MICRO2+ is a small, compact battery operated ambulatory pulse oximeter.

The hand-held INFINITY MICRO2+ is a redesign of the MICRO2 (K913489) used for the noninvasive measurement of the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate with the use of an oxygen transducer (sensor).

The SpO_2 algorithm is essentially the same as that of the predicate (K980882), but enhanced for greater artifact, motion and low perfusion tolerance. A range of compatible sensors is available for use with the INFINITY MICRO2+.

The INFINITY MICRO2+ can be connected to a Siemens INFINITY Telemetry transmitter (K972714) or to a customer's personal computer for the display and printing of SpO_2 trend information. The device is intended to provide continuous, non-invasive SpO_2 monitoring for neonatal, pediatric and adult patient populations in health care environments where patient care is provided by licensed health care professionals.

5. Intended Use:
The MICRO2+ is intended for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate during both no motion and motion conditions, and for patients who are well or poorly perfused, using a range of compatible sensors. The device will produce visual and aural alarms if these parameters vary beyond preset limits

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6. Table of Device Similarities and differences to predicate device

	Predicate Device	*Predicate Device*	*Applicant*	*Explanation of Differences*
Manufacturer	***Siemens Medical Systems MICRO2***	***Siemens Medical Systems SC 7000 / SC 9000XL***	***Siemens Medical Systems INFINITY MICRO2+***	
510(k) Number	***K913489***	***K980882***	***To be determined***	
Intended Use	To non-invasively measure functional oxygen saturation of arterial hemoglobin and pulse rate using a range of compatible sensors and to produce visual and aural alarms if these parameters vary beyond preset limits.	The intended use of the SC 7000 and SC 9000XL INFINITY Modular Bedside Monitoring Series is to measure heart rate, respiration rate, invasive pressure, non-invasive pressure, arrhythmia, temperature, *arterial oxygen saturation and pulse rate*, cardiac output, central apnea, ST segment analysis, and 12-Lead ST Segment Analysis. This device will produce visual and audible alarms if any of these parameters vary beyond preset limits and produce timed or alarm recordings. This device will connect to a Siemens R50 Bedside Recorder, either directly or via the Infinity network.	The MICRO2+ is intended for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate during both no motion and motion conditions, and for patients who are well or poorly perfused, using a range of compatible sensors. The device will produce visual and aural alarms if these parameters vary beyond preset limits.	Same SpO2 and Pulse Rate algorithm as K980882 with modifications, including motion detection
Intended Population	Adult/pediatric	Adult/pediatric/neonatal	Same as K980882	
Intended Environment	Clinical environment	For use in an environment where patient care is provided by Healthcare Professionals	Same as K980882	
Clinical and non-clinical testing			Clinical and bench testing performed demonstrate that the INFINITY MICRO2+ is as safe and effective as the predicate devices	

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7. Assessment of non-clinical performance data for equivalence: Section S

8. Assessment of clinical performance data for equivalence: Section T

9. Biocompatability:
Not applicable

10. Sterilization:
Not applicable

11. Standards and Guidances: Section U

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2002

Ms. Penelope H. Greco
Siemens Medical Solutions USA, Incorproated
Division of EM-PCS
16 Electronics Avenue
Danvers, Massachusetts 01923

Re: K012770
Trade/Device Name: Infinity Micro2+
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 25, 2002
Received: April 29, 2002

Dear Ms. Greco:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

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

Enclosure

K012770

Indications for Use:

The MICRO2+ is indicated for the continuous, non-invasive monitoring of functional oxygen saturation of arterial hemoglobin and pulse rate during both no motion and motion conditions, and for patients who are well or poorly perfused.

MRI Compatibility Statement:
The Siemens INFINITY MICRO2+ is not intended for use in a MRI magnetic field.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Dev
K012770