K031361

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

CADD® High-Volume Administration Set with FlowStop

April 29, 2003

MAY 23 2003

I. GENERAL INFORMATION

Applicant's Name and Address:	Deltec, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	Lisa J. Stone Manager, Regulatory Affairs
Common/Usual Name:	Administration Set
Proprietary Name:	CADD® High-Volume Administration Sets with FlowStop
Equivalence Device Comparison:	CADD® High-Volume Administration Sets and GemStar™ Pump Set

II. DEVICE DESCRIPTION

The CADD® High-Volume Administration Sets with FlowStop is a modification to the current CADD® High-Volume Administration Sets. The sets will incorporate a set-based free flow protection component (i.e. FlowStop) that is designed to occlude the tube if the set is accidentally placed onto the pump incorrectly or becomes detached from the pump.

The FlowStop will be located on the set housing, which is attached to the pump. The set will be provided to the user in an open state. Before the set can be attached to the pump, the "CLIP" must be removed to activate the FlowStop. However, after attaching the set to the pump, the user can still remove the set from the pump and prime it by holding the FlowStop in the open position.

The Add-on Anti-siphon Valve, which is included with current sets will not be provided with the new sets. This valve is no longer necessary because of the addition of the FlowStop.

III. INTENDED USE OF THE DEVICE

The CADD® High-Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag.

IV. DEVICE COMPARISON

The CADD® High-Volume Administration Sets with FlowStop is similar in design, function, and intended use to the current CADD® High-Volume Administration Sets. These sets are identical except for the addition of the FlowStop and the removal of the anti-siphon valve.

The sets will incorporate a set-based free flow protection component (i.e. FlowStop) that is designed to occlude the tube if the set is accidentally placed onto the pump incorrectly or becomes detached from the pump. This is similar to the flow stop on the GemStar™ Pump Set.

V. SUMMARY OF STUDIES

A. Functional Testing

In-vitro testing was conducted on the CADD® High-Volume Administration Set with FlowStop.

Biocompatibility testing was performed on the new FlowStop components.

B. Clinical Studies

Clinical studies were not deemed necessary regarding the CADD® High-Volume Administration Set with FlowStop due to their similarity in materials, design and function to the current CADD® High-Volume Administration Sets and the GemStar™ Pump Set.

C. Conclusions Drawn from the Studies

The results of the testing indicated that the CADD® High-Volume Administration Set with FlowStop function according to specifications and the materials used in the device are biocompatible. Therefore, the product is considered acceptable for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

Ms. Lisa Stone
Manager, Regulatory Affairs
Deltec, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K031361
Trade/Device Name: CADD® High-Volume Administration Set with FlowStop
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: April 29, 2003
Received: May 8, 2003

Dear Ms. Stone:

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 (301) 594-4618. 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K031361

510(k) Number (if known): _____

Device Name: CADD® High-Volume Administration Set with FlowStop

Indications for Use:

"The CADD® High-Volume Administration Set is designed for use with the CADD-Prizm® pump to allow fluid delivery from an IV bag."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K031361

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