K993463

JAN - 4 2000

Custom Assemblies, Inc.
Your Quality Partner

Non-Confidential Summary of Safety and Effectiveness

October 11, 1999

Custom Assemblies, Inc.
306 E. Brown St.
P.O. Box177
Pine Level, NC 27568

Tel - (919) 550-9620

Fax - (919) 550-3817

Official Contact:	Jack Peacock - President
Proprietary or Trade Name:	Extension set
Common/Usual Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set
Device:	Extension set
Predicate Devices:	R-Group - K940319
	The Kipp Group - I.V. Administration Set - K991932

Device Description:

The Custom Assemblies Extension Set is a tubing set with various connectors, and accessories, such as drip chambers, infusion line filters, clamps, integral check valves, spikes, Y-site injection sits used as an extension of a fluid pathway for I.V. administration.

Intended Use:

Indicated Use --	Indicated as a single, use, sterile device for use in I.V. therapy when an extended fluid path is required for administration.
Environment of Use --	Hospital, Emergency Services, Home settings, wherever I.V. administration is utilized.

Comparison to Predicate Devices:

Please change our mailing address to:

PO BOX 177
Pine Level, NC 27568

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Attribute	Custom Assemblies	R-Group K940319	Kipp Group K991932
Use			
Indicated for I.V. therapy and administration	Yes	Yes	Yes
Used as fluid path way	Yes	Yes	Yes
Single patient use	Yes	Yes	Yes
Environment where I.V therapy is indicated	Yes	Yes	Yes
Design			
Tubing of various lengths and diameters	Yes	Yes	Yes
Connectors - luer fittings	Yes	Yes	Yes
Assembled with - drip chambers, clamps, infusion line filter, spikes, check valves, caps	Yes	Yes	Yes
Offered sterile	Yes	Yes	Yes
Materials			
Tubing - PVC Class VI	Yes	Yes	Yes
Accessory components Polycarbonate, Polypropylene, PVC	Yes	Yes	Yes
Performance Standards - Specifications			
None required under Section 514	Yes		Yes

Differences between Other Legally Marketed Predicate Devices

There are no significant differences between the intended device and the predicates - R-Group - K940319 and The Kipp Group - K991932.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2000

Custom Assemblies, Inc.
c/o Mr. Paul E. Dryden
on behalf Custom Assemblies, Inc.
Promedic, Inc.
6329 W. Waterview Court
McCordsville, Indiana 46055

Re: K993463
Trade Name: Intravascular Administration Set
Class: II
Product Code: FPA
Dated: November 19, 1999
Received: November 23, 1999

Dear Mr. Dryden:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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" (21 CFR 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/dsmamain.html".

Sincerely yours,

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

Enclosure

K993463

Pursuant to the Notice of February 6, 1996 regarding listing of Indications for Use on a separate sheet, the following is per that request.

510(k) Number: _____ (to be assigned)

Device Name: I.V. Administration Sets

Intended Use: Indicated as a single use, sterile device for use in I.V. therapy when an extended fluid path is required for administration.

Environment of use: Hospital, Emergency Medical Services, Home care settings, wherever I.V. fluid administration may be indicated.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)

Melissa Cavanaugh
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993463