

JAN 23 1998

510(k) Notification
September 30, 1997

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

K973713

Submitted By: CardioVascular Dynamics, Inc.
13700 Alton Parkway
Irvine, CA 92618
Contact Person: Pamela Misajon
(714) 595-7333

Summary Preparation: September 30, 1997

Device: P.D. Access™ Percutaneous Doppler
Vascular Access Device
P.D. Access Dual Frequency Monitor

Classification Name: Diagnostic Ultrasound Transducer

Predicate Devices:

Doppler Needle:

CVD
18 gauge *SmartNeedle*®
#K903625. SE Date: November 7, 1990

CVD
18 gauge *SmartNeedle*
#K913746. SE Date: December 17, 1991

CVD
20 gauge *SmartNeedle*
#K913941. SE Date: February 27, 1992

CVD
20 gauge *SmartNeedle*
#K940804. SE Date: June 10, 1994

CVD
22 gauge P.D. Access/*SmartNeedle*
#K963989. SE Date: April 24, 1997

Introducer Catheter:

CVD
22 gauge P.D. Access/*SmartNeedle*®
#K963989. SE Date: April 24, 1997

TFX Medical
Introducer Catheter
#K851141

The P.D. Access™ device is intended to be used in conjunction with the P.D. Access Dual Frequency Monitor for general vascular use.

The P.D. Access device is intended for general vascular use for audibly indicating the Doppler response to blood flow within an artery or vein. The indications and intended use for the P.D. Access device is the same as the predicate devices manufactured by CardioVascular Dynamics (i.e., P.D. Access/SmartNeedle). Product technology, performance characteristics, specifications, components and materials of the P.D. Access device are similar to those of predicate devices.

Testing of the P.D. Access device included dimensional, strength, ultrasonic performance and biocompatibility testing. These tests demonstrated that all of the items tested were within specification tolerances. There were no failures during these tests. Overall performance was safe and effective.

Comparisons were made based on the size, construction, materials and use. Refer to the comparison chart enclosed.

There are many commercially available Doppler devices indicated for monitoring of blood flow within the general vasculature which were marketed prior to promulgation of the Medical Device Amendments (May 28, 1976) or have been found substantially equivalent to pre-enactment devices. The P.D. Access device is intended for use in the same manner. In particular, the P.D. Access device is equivalent in indications and intended use to devices manufactured by CardioVascular Dynamics, formerly manufactured by Advance Cardiovascular Systems (ACS).

The P.D. Access Monitor was originally listed by Advanced Cardiovascular Systems (ACS) under the name *SmartNeedle*® Monitor on document number A877515. The P.D. Access device was originally listed by ACS under the name *SmartNeedle* on document number A877516. These devices were delisted by ACS, July 19, 1996. The P.D. Access Monitor is registered under the name *SmartNeedle* by CVD under document A899719 and the P.D. Access device under the name *SmartNeedle* document number A999797.

COMPARISON CHART

Parameter	24/26 Gauge P.D. Access™	22 Gauge P.D. Access SmartNeedle®	20 Gauge SmartNeedle	18 Gauge SmartNeedle
510(k) #	Not Applicable	#K963989	#K913941 #K940804	#K903625 #K913746
Trade Name	P.D. Access Device	P.D. Access or SmartNeedle®	SmartNeedle	SmartNeedle
Model #	78110 78120	78050 78060 78070	77010	75010
Frequency	30 MHz	14.3 MHz	14.3 MHz	14.3 MHz
Mode	Continuous	Continuous	Continuous	Continuous
Monitor	P.D. Access Dual Frequency 14.3 / 30 MHz	P.D. Access or SmartNeedle	P.D. Access or SmartNeedle	P.D. Access or SmartNeedle
Indication	Blood Flow	Blood Flow	Blood Flow	Blood Flow
Construction	Probe Needle ONC Introducer	Probe Needle ONC Introducer Peel Away Introducer	Probe Needle	Probe Needle
Output/Display	Audible	Audible	Audible	Audible
Probe Diameter	.010 inches	.016 inches	.016 inches	.035 inches
Needle Diameter	24/26 Gauge	22 Gauge	20 Gauge	18 Gauge
Introducer Diameter	22/24 Gauge	22 Gauge	Not Applicable	Not Applicable



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pamela Misajon
Manager, Regulatory Affairs
and Quality Assurance
Cardio Vascular Dynamics, Inc.
13700 Alton Parkway
Irvine, California 92618

JAN 23 1998

Re: K973713
P.D. Access™ Vascular Access Device
24/26 Gauge and P.D. Access™ Dual Frequency Monitor
Dated: December 9, 1997
Received: December 10, 1997
Regulatory Class: II
21 CFR 892.1570/Prococode: 90 ITX

Dear Ms. Misajon:

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. You may, therefore, market the device, subject to the general controls provisions Act (Act). The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the P.D. Vascular Access Device, as described in your premarket notification:

Transducer Model Numbers

78120, 78110

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 requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report.

This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

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

This letter will allow you to begin marketing your device as described in your 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 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) 594-4591. 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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact **Rodrigo C. Perez** at (301) 594-1212.

Sincerely yours,

for David G. Seymour

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K973713

Device Name: P.D. Access Vascular Access Device
P.D. Access Dual Frequency Monitor

Indications For Use:

P.D. Access Device: Is intended for use when blood flow must be detected for percutaneous vessel cannulation. The vessel must be of a caliber which would normally be punctured with a needle and introducer of this size or larger

These additional probe/needle models are being incorporated to broaden the product line in order to accommodate both user preference and patient anatomies for all age groups.

P.D. Access Monitor: Is intended for use to audibly indicate the doppler response of blood flow within an artery or vein. It is intended for use only in conjunction with the P.D. Access Vascular Access Device.

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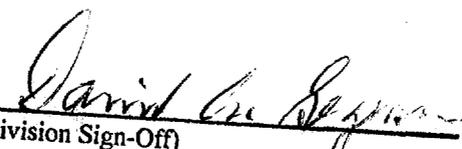
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K973713

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Petal										
Abdominal										
Intra-operative (Specify)										
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular					X					
Laparoscopic										
Musculo-Skeletal Conventional										
Musculo-Skeletal Superficial										
Other (Specify)										

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)
 Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Johnson

 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices
 510(k) Number K973713

Prescription Use (Per 21 CFR 801.109)