APR 24 1997

SECTION 2 - 510(K) SUMMARY K963989

Submitted By:

CardioVascular Dynamics Incorporated (CVD)
13900 Alton Parkway, Suite 122
Irvine, CA 92618
714-457-9546
Contact: Michael Crocker

Summary Preparation: September 18, 1996

Device: P.D. Access™ Vascular Access Device
*Smart*Needle® Vascular Access Device

Classification Name: Ultrasonic Blood Flow Monitor

Predicate Devices:

CVD
18 gauge *Smart*Needle®
K903625
SE Date: November 7, 1990

CVD
18 gauge *Smart*Needle®
K913746/A
SE Date: December 17, 1991

CVD
20 gauge *Smart*Needle®
K913941/A
SE Date: February 27, 1992

CVD
20 gauge *Smart*Needle®
K940804
SE Date: June 10, 1994

Introducers

TFX Medical
Over the Needle Splittable Catheter
K920208

TFX Medical
Introducer Catheter
K851141

The P.D. Access™ / SmartNeedle® Device is intended to be used in conjunction with the *Smart*Needle® Monitor for general vascular use. The *Smart*Needle® Monitor will also be marketed as the P.D. Access™ Monitor; and the Monitor

graphics and labeling will be changed to reflect the name. Other than the name, the Monitors will be equivalent. There will be no change in safety and efficacy.

The P.D. Access™ / SmartNeedle® Device is indicated and intended for general vascular use for monitoring the flow of blood within the vasculature. The indications and intended use for of the P.D. Access™ / SmartNeedle® Device are the same as predicate devices manufactured by CardioVascular Dynamics (the *Smart*Needle®). Product specifications, components and materials of the P.D. Access™ / SmartNeedle® Device are similar to those of predicate devices.

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

Comparisons are made based on the size, construction, materials and use. See the following comparison table.

COMPARISON TABLE: ULTRASOUND DEVICES

	22 gauge P.D. Access™ *Smart*Needle®	22 gauge P.D. Access™ *Smart*Needle® with ONC introducer	22 gauge P.D. Access™ *Smart*Needle® with Peel Away introducer	20 gauge *Smart*Needle®	18 gauge *Smart*Needle®
510(k) #				K913941/A K940804	K903625 K913746/A
Trade Name	P.D. Access™ or *Smart*Needle®	P.D. Access™ or *Smart*Needle®	P.D. Access™ or *Smart*Needle®	*Smart*Needle®	*Smart*Needle®
Model #	78050	78060	78070	77010	75010
Frequency	14.3 MHz	14.3 MHz	14.3 MHz	14.3 MHz	14.3 MHz
Mode	Continuous	Continuous	Continuous	Continuous	Continuous
Monitor	P.D. Access™ or *Smart*Needle® Monitor	P.D. Access™ or *Smart*Needle® Monitor	P.D. Access™ or *Smart*Needle® Monitor	P.D. Access™ or *Smart*Needle® Monitor	P.D. Access™ or *Smart*Needle® Monitor
Indication	Blood flow	Blood flow	Blood flow	Blood flow	Blood flow
Construction	Needle/ Probe	Introducer/ Needle/ Probe	Introducer/ Needle/ Probe	Needle/ Probe	Needle/ Probe
Output/ Display	Audible	Audible	Audible	Audible	Audible

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™ / SmartNeedle® Device is intended for use in the same manner. In particular, the P.D. Access™ / SmartNeedle® Device is equivalent in indications and intended use to devices manufactured by CardioVascular Dynamics, formerly manufactured by Advance Cardiovascular Systems (ACS).

The *Smart*Needle® Doppler Monitor was originally listed by Advanced Cardiovascular Systems (ACS) under document number A877515. The *Smart*Needle® Introducer Needle for Doppler Monitoring was originally listed by Advanced Cardiovascular System (ACS) under document number A877516. These devices were delisted by ACS, July 19, 1996. The *Smart*Needle® Doppler Monitor is registered by CVD under document number A899719 and the *Smart*Needle® Introducer needle for Doppler monitoring under document number A999797. This is substantiated in the Comparison Table. Product literature is included.