

K971577

SECTION 3 - 510(k) SUMMARY

Submitted By: CardioVascular Dynamics Incorporated (CVD)
13700 Alton Parkway
Irvine, CA 92618
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Contact: Pamela Misajon

JUN 18 1997

Summary Preparation: April 18, 1997

Device: FOCUS™-PV Balloon Dilatation Catheter

Classification Name: Catheter, Peripheral, Balloon Type

Predicate Device: Match 35™ PTA Balloon Catheters
PTA Catheters: Schneider

Total Cross™ Balloon Dilatation Catheter
Schneider

MS Classique™ Balloon Dilatation Catheter
Medi-tech

Ultra-Thin™ Balloon Dilatation Catheter
Medi-tech

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K944016
SE Date: December 20, 1994

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K952064
SE Date: June 21, 1995

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K954313
SE Date: December 1, 1995

INTENDED USE

COMPARISON TO PREDICATE DEVICES:

- The intended use of the CVD FOCUS™-PV catheter as it appears in the labeling is as follows:

"FOCUS™-PV Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty of the large vessels of the renal, femoral, popliteal, tibial, peroneal, iliac and profunda arteries and for treatment of obstructive lesions of native or synthetic arterovenous dialysis fistulae."

- The intended use of the predicate Schneider Match 35™ catheter as it appears in the labeling is as follows:

"Schneider MATCH 35™ Percutaneous Transluminal Angioplasty (PTA) Catheters are recommended for use in percutaneous transluminal angioplasty of narrowed segments of peripheral vessels. This catheter is not designed for use in the coronary arteries. Any use other than those indicated is not recommended."

- The intended use of the predicate Schneider Total Cross™ .021 catheter as it appears in the labeling is as follows:

"Schneider TOTAL CROSS™ .021 Percutaneous Transluminal Angioplasty (PTA) Catheters are recommended for use in percutaneous transluminal angioplasty of narrowed segments of peripheral vessels. This catheter is not designed for use in the coronary arteries. Any use other than those indicated is not recommended."

- The intended use of the predicate Medi-tech MS Classique™ catheter as it appears in the labeling is as follows:

"The MS Classique Balloon Catheter is recommended for: percutaneous transluminal angioplasty of the aorta, superior mesenteric, subclavian, brachial, iliac, femoral, popliteal and renal arteries; percutaneous transhepatic biliary tract stenosis and/or sphincter stenosis, use in conjunction with choledochojejunostomy performed with a Roux-en Y; transureteral and transurethral dilatation of strictures in the urinary tract."

- The intended use of the predicate Medi-tech Ultra-Thin™ catheter as it appears in the labeling is as follows:

"Ultra-thin Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty of the iliac, Femoral and Renal Arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Ultra-thin Catheters are not indicated for use in coronary arteries."

- The intended use of the CVD FOCUS catheter as it appears in the labeling is as follows:

"FOCUS Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty of the small vessels of the femoral, popliteal, tibial, peroneal, and profunda arteries."

DISCUSSION

All of the above catheters are recommended for balloon angioplasty of the peripheral vessels. All predicate devices listed have been through the 510(k) process.

The FOCUS™-PV Balloon Dilatation Catheter is intended to be used in the same anatomical sites as the predicate devices.

TABLE 1
COMPARISON OF FOCUS
WITH CURRENTLY MARKETED PTA CATHETERS

MANUFACTURER	CardioVascular Dynamics	CardioVascular Dynamics	Schneider	Schneider	Medi-tech	Medi-tech
Product Name	FOCUS Balloon Dilatation Catheter	FOCUS -PV Balloon Dilatation Catheter	Match 35 PTA Balloon Dilatation Catheter	Total Cross PTA Balloon dilatation Catheter	MS Classique Balloon Dilatation Catheter	MS Ultra-Thin Balloon Dilatation Catheter
Balloon size	2.5 - 4. mm (0.5 incr.)	4.0/5.0-7.0/8.0 mm (1.0 incr)	3.0 -- 10.0 mm	2.0 - 8.0 mm	4.0 - 10.0 mm	4.0 - 10.0 mm
Balloon Length	20, 25 mm	25, 30, 40 mm	20, 40, 80, 100 mm	20, 40, 80 mm	25, 40, 80, 100 mm	20, 40, 80, 100 mm
Shaft Size	3.5F proximal 3.0F distal	4.3F/5.0F	4.3F/5.0F	4.3F	4.8F and 5.2F	5.0F
Shaft Length	135 cm	75 - 150 cm	75 - 150 cm	95 - 150 cm	75 - 120 cm	75 - 150 cm
Balloon Materials	Polyethylene/PET	Polyethylene Terephalate (PET)	Polyethylene Terephalate (PET)	Polyethylene/ PET	Polyethylene Terephalate (PET)	Polyethylene Terephalate (PET)
Shaft	Polyethylene	Nylon	Polyester	Polyester	Polyester	Polyester
Guidewire size (Max)	0.014 in.	0.018/0.035 in.	0.035 in.	0.021 in.	0.035 in.	0.035 in.

Reason for Premarket Notification:

This 510(k) is for a modification to an existing device, 510(k) number K963688 SE Date March 28, 1997.

Predicate Devices:

Schneider
Match 35™ PTA Balloon catheter

Schneider
Total Cross™ Balloon dilatation Catheter

Medi-tech
MS Classique™ Balloon Dilatation Catheter

Medi-tech
Ultra-Thin™ Balloon Dilatation Catheter

CardioVascular dynamics, Inc.
FOCUS™ Balloon Dilatation Catheter
510(k) number K944016
SE Date: December 20, 1994

510(k) number K952064
SE Date: June 21, 1995

510(k) number K954313
SE Date: December 1, 1995



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1997

Ms. Kimberly Sailer
Product Regulation Manager
CardioVascular Dynamics, Inc.
13700 Alton Parkway
Irvine, California 92618

Re: K971577
FOCUS™ - PV Balloon Dilatation Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: April 18, 1997
Received: April 21, 1997

Dear Ms. Sailer:

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 Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4648. 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971577

Device Name: FOCUS PV BALLOON DILATATION CATHETER

Indications For Use:

FOCUS™-PV Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty of the large vessels of the renal, femoral, popliteal, tibial, peroneal, iliac and profunda arteries and for treatment of obstructive lesions of native or synthetic arterovenous dialysis fistulae.



(Signature)
Cardiovascular, Respiratory,
Devices

510(k) number K971577

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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)