This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

J.1. Submitter's information

Submitter's name:	PORGES S.A.
Submitter's address:	Centre d'Affaires La Boursidière 92357 Le Plessis Robinson – France
Contact person:	Mr Bernard ISMAEL Regulatory Affairs Manager
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Date of preparation:	February, 2002

J.2. Device name

Classification name:	Catheter, ureteral, gastro-urology
Common / Usual name:	Ureteral catheters
Proprietary name:	PORGES™ Ureteral catheters

J.3. Predicate devices

The PORGES™ Ureteral catheters are substantially equivalent to the PORGES™ pre-amendment range of ureteral catheters, C.R. Bard Inc. Urological Division's currently marketed ureteral catheter line and Bard® Flexible Tip Ureteral catheter (K950300). PORGES S.A.. is not aware of any information suggesting that C.R. Bard Inc. ureteral catheters are not legally marketed. Ureteral catheters may also be referred to as ureteric catheters, both denominations being equally used within the medical profession.

J.4. Description of the Device

The PORGES™ Ureteral catheters consist of a single lumen catheter in medical grade radiopaque polymer, graduated every cm along 50 cm, and fitted with either a metal or a polymer removable stylet or no stylet. The stylet allows straightening of the catheter for easier insertion. A wax knob is added on the external end of the stylet for easy retreat of the stylet. The coudé tip catheters are fitted with a silicone stop ring on the stylet between the catheter and the wax knob to hold the renal tip of the stylet away from the catheter's renal tip.
The ureteral catheters are available with different types of renal tips and in sizes ranging from 03 FR to 12 FR.
The preamendment devices have been designed for drainage and for R.U.P. (retrograde uretero-pyelography).
PORGES has validated the following uses for the new range of ureteral catheters :

- drainage
- R.U.P. (= retrograde uretero pyelography)
- interventional ("per operating") use with a Seldinger guide wire (not supplied)

The predicate devices Bard® Flexible Tip ureteral catheters (K950300) and C.R. Bard's currently marketed devices are designed for the same intended use.
The PORGES™ Ureteral catheters are supplied sterile and for single use only.

J.5. Intended use of the Device

The PORGES™ Ureteral catheters are used for ureteral catheterisation:

- drainage catheters: straight catheters with bevel, olive or cylindrical tip, elbowed catheter with olive tip
- catheters for retrograde ureteropyelography (R.U.P.): Chevassu, cone or Braasch
- interventional catheters: flush, open straight, open elbowed. The appropriate guide-wire size for each catheter is shown on the box.

J.6. Technological characteristics

The PORGES™ Ureteral catheters have similar technological and performance characteristics to the predicate devices. The PORGES™ Ureteral catheters are similar as it concerns its materials to PORGES and C.R. Bard's currently marketed ureteral catheters and to the Bard Flexible tip ureteral catheter (K950300). All are made of medical grade thermoplastic material. The choice of either a polyvinyl chloride, polyamide, polyurethane or PEBA (polyether block amide) catheter or metal or polymer stylet may provide a slight difference in stiffness, which does not affect clinical properties, but may be preferred by practioners according to the method of use.
The polyvinyl chloride and polyamide mixtures which are used for the manufacturing of most PORGES Ureteral catheters are the same as those used since 1971 for the manufacturing of the PORGES pre-amendment devices.
The straight open tip of the interventional ureteral catheters allows placement over a guide-wire. The straight open tip is similar in performance as the straight whistle tip of both Porges' and Bard's currently marketed catheters.

J.7. Test Summary

The PORGES™ Ureteral catheters referenced in this submission are held to the same design, manufacture, and performance specifications as the predicate devices. Substantial equivalence of the devices with respect to functional performance has been demonstrated by mechanical/physical testing.
The following tests have been performed :

- Flow rate
- Tensile strength
- Tear strength of bulbs (Chevassu and cone-tip catheters)
- Passage of contrast medium

The PORGES™ Ureteral catheters have successfully passed biocompatibility testing per ISO 10993-1.

J.8. Conclusion.

The biocompatibility and mechanical/physical tests confirm the safety and effectiveness for these devices is assured and these devices perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2002

Mr. Bernard ISMAEL
Regulatory Affairs Manager
PORGÈS S.A.
Centre d'Affaires La Boursidière
92357 Le Plessis-Robinson Cedex
FRANCE

Re: K021856
Trade/Device Name: PORGÈS™ Ureteral Catheters Models ACN6xx, ACN5xx, AC5B, AC5C07, ACP5xx, ACP2xx, ACP3xx, ACP4xx, and ACP6xx
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 EYB
Dated: September 24, 2002
Received: October 7, 2002

Dear Mr. ISMAEL:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section F: Indications for Use Statement

510(k) Number (if known): K021856

Device Name: PORGES™ Ureteral catheters

Indications for use:

The PORGES™ Ureteral catheters are used for ureteral catheterisation:
- drainage catheters: straight catheters with bevel, olive or cylindrical tip, elbowed catheter with olive tip
- catheters for retrograde ureteropyelography (R.U.P.): Chevassu, cone or Braasch
- interventional catheters: flush, open straight, open elbowed. The appropriate guide-wire size for each catheter is shown on the box.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David A. Segman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021856