OCT 17 2002

Section J: 510(k) Summary

PORGES™ Silicone double loop ureteral stent 510(k) submission

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
Contact person's phone: + 33 1 46 01 32 06
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Contact person's email: bernard.ismael@porges.com
Date of preparation: November, 2001

J.2. Device name

Classification name: Splint, ureteral (78 FAD)
Common / Usual name: Double loop ureteral stent
Proprietary name: PORGES™ Silicone double loop ureteral stent

J.3. Predicate devices

The PORGES™ Silicone double loop ureteral stent is substantially equivalent to the PORGES ureteral stent from BIVONA and the VORTEK™ and BIOSOFT™ ureteral double loop stents.

J.4. Description of the Device

The PORGES™ Silicone double loop ureteral stents are supplied in kits, containing the following components:

- A double loop ureteral stent and an obturator
- A guide-wire, where applicable
- A pusher (where applicable supplied with a clamp)

J.5. Intended use of the Device

The PORGES™ Silicone double loop ureteral stent is intended for the exact same use as the current PORGES ureteral stent (K881744) and VORTEK™ and BIOSOFT™ ureteral double loop stents (K981591).
The PORGES™ Silicone double loop ureteral stent is used for :
Standard versions

- Drainage of the upper urinary tract over fistulas or ureteral obstructions (e.g. periureteral tumour)
- Cicatrisation stent

Reinforced versions: Management of ureteral stenoses

- Partial enlargement of the diameter: localised stenoses connected with ureteropelvic junction syndrome
- Total enlargement of the diameter: stenoses over all or part of the ureter

J.6. Technological characteristics

The PORGES™ Silicone double loop ureteral stent has similar technological and performance characteristics to the predicate devices. The catheter is manufactured entirely from silicone elastomer as for the predicate devices. The ureteral stents are made of the same yellow silicone tubing as the predicate silicone ureteral stent. They are steerable or non-steerable, and radiopaque.
Most references are available in 06/07/08 CH/Fr and in different lengths, ranging from 12 to 30 cm.
Renal and vesical loops may be either closed or open. The straight section may be totally or partially reinforced.
The eyes are lateral and staggered and are situated every 2 cm along the entire length of the stent (except for the no eye on the straight section version).

The ureteral stents have either a fixed core guide-wire, a movable core guide-wire or no guide-wire, depending upon the method of use.

The steerable ureteral stents have connectable pushers, and the non-steerable stents have simple pushers. The ureteral stent kits are supplied sterile and for single use only.

J.7. Testing and results

The PORGES™ Silicone double loop ureteral stent referenced in this submission is held to the same design, manufacture, and performance specifications as the predicate devices. Substantial equivalence of the devices with the VORTEK™ and BIOSOFT™ ureteral double loop stents (K981591) with respect to functional performance has been demonstrated in conformity with the FDA "Guidance for the content of premarket notifications for ureteral stents" dated February 10th, 1993. Where available, standard specifications are used to establish test methods. Tests are conducted in conditions similar to most unfavorable conditions of medical/surgical practice.
The following tests have been performed :

- Flow rate through the stent
- Elongation and tensile strength of the stent after a 18 month soaking period in different buffer solutions.
- Loop strength

The PORGES™ Silicone double loop ureteral stent passes biocompatibility testing per ISO 10993-1.
The data currently available for the silicone stents enables them to be validated for an implantation period of up to 12 months. The decision to leave the withdrawal wire in place on the stent must be taken in relation to the planned implantation period.
Periodic examinations via radiographic and/or cystoscopic means are recommended to evaluate stent efficiency and to observe for possible complications. The stent must be replaced if encrustation hampers drainage, if there is indication of infection in the area of the stent or in case of migration or rupture.

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
92 357 Le Plessis-Robinson Cedex
FRANCE

Re: K013921
Trade/Device Name: PORGÈS™ Silicone Double Loop Ureteral Stent
Regulation Number: 21 CFR §876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: August 8, 2002
Received: August 15, 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): K013921

Device Name: PORGES™ Silicone double loop ureteral stent

Indications for use:

Standard versions

- Drainage of the upper urinary tract over fistulas or ureteral obstructions (e.g. periureteral tumour)
- Cicatrisation stent

Reinforced versions

Management of ureteral stenoses

- Partial enlargement of the diameter: localised stenoses connected with ureteropelvic junction syndrome
- Total enlargement of the diameter: stenoses over all or part of the ureter

(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 G. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013921