AUG 0 8 2002

Section V. 510(k) SUMMARY of Safety and Effectiveness

Sponsor:	Boston Scientific/ Microvasive One Scientific Place Natick, MA 01760-1537
Contact Person:	Janet A. McGrath Sr. Global Regulatory Affairs Specialist **OR** Lorraine M. Hanley Director, Global Regulatory Affairs
Submission Date:	October 31, 2001
Common/Usual Name:	Ureteral Stent, Indwelling Ureteral Catheter
Trade/Proprietary Name:	To Be Determined
Device Classification and Name:	Class II: Ureteral Stent, 21CFR 876.4620
Indications for Use:	The proposed device is intended to facilitate the passage of urine from the kidney to the bladder.
Substantial Equivalence:	The proposed device is substantially equivalent to ureteral stents classified by the Code of Federal Regulations 21CFR 876.4620 and FDA product code 78FAD, based on a review of the FDA's 510(k) Decision-making Process.
Product Testing:	To determine appropriate testing for the device, FDA's Draft Guidance Ureteral Stents was utilized. The functional bench test results demonstrate that the proposed device is substantially equivalent to the predicate devices in terms of characteristics tested. The proposed device meets the biocompatibility requirements of ISO 10993 for its intended use. A clinical trial involving 88 patients was conducted on the placement of the TUDS device.
Device Description:	The Microvasive® Temporary Ureteral Drainage Stent is 6 Fr x 26.5 cm, with an open-ended coil at each end. The stent is an extruded polymeric tube made of a reversible cross-linked alginate polymer with an incorporated radiopacifier. The device is placed, using standard ureteral stent placement techniques that can be placed transurethrally, percutaneously or via open surgery using endoscopic and/or radiographic techniques.

Clinical Studies

The purpose of the clinical study to evaluate the safety and effectiveness of the Microvasive™ Temporary Ureteral Drainage Stent (TUDS) to facilitate short-term drainage of fluid from the kidney to the bladder.

The clinical study was designed as a prospective, single-arm, multi-center trial. The study included 6 investigative sites that could enroll a maximum of 88 total subjects. Each subject had only one TUDS placed following uncomplicated ureteroscopy.

Subjects with a TUDS successfully placed underwent assessments for device presence, position, and morphology at 1, 2, 7 and 14 days post placement. The exams at days 7 and 14 were not required, if there was no evidence of the TUDS at the preceding exam. All subjects in whom a TUDS was successfully placed were assessed at 30 days to evaluate normal renal drainage on the affected side and assess possible adverse events. If the device was still present in the urological system at day 30, the patient was evaluated at day 60 and day 90.
The study had two primary endpoints:

- *Primary effectiveness endpoint –*

Study success defined as adequate short term drainage defined as the presence of the stent in the ureter and the lack of surgical or other intervention to treat symptoms on the stented side during the first 48 hours following placement.

- *Primary safety endpoint –*

Assessment of adverse events (incidence, relationship to device, severity)

- *Alternate Endpoint-*

Overall clinical success was also calculated and was defined as adequate drainage with no intervention (regardless of stent presence) and no definitely device-related serious adverse events (SAEs) throughout the 90 day follow-up period.

<u>Study</u>

A total of 88 patients had the TUDS placed following uncomplicated ureteroscopy. All patients were ≥ 18 years of age and required short-term stenting to facilitate drainage.

Radiological assessments (i.e., KUB films) for presence, position, and morphology of the device and assessment of adverse events were performed at the scheduled follow-up visits. All subjects were also assessed at 30 days post-placement to evaluate normal renal function by intravenous pyelogram (IVP) on the affected side and to assess adverse events.

A total of 88 patients had the TUDS placed. The study period was 30 days for those patients who successfully passed the TUDS within 30 Days. If the stent remained present at the day 30 follow-up visit, the patient returned for Day 60 and Day 90 follow-up visits for additional monitoring.

There were no deaths among the TUDS patients studied. There were no reported unanticipated adverse events. Adverse events reported for the TUDS patients were similar to those reported in the literature for plastic ureteral stents. See Tables in the Adverse Events section for a listing of the adverse events observed in the study patients. Mean time to eliminate the TUDS from the body was 21 days. **Warning:** Clinical study shows that stent fragments may remain in the urinary system for over 90 days and may require removal.

Study success was found to be 78.2% (68/87; 17 absence of stent and 3 interventions occurred, within the first 48 hours; 1 patient had both an absence of stent and intervention). The Alternate Endpoint, *Overall clinical success* was found to be 94.3% (83/88) with the 90 day study period. Tables 1 to 3 summarize the demographic, follow-up study visits, and clinical endpoint results for the TUDS study.

Table 1
Demographic Information

Category	Value ± SD, (range), n=88
Gender (%male)	65.9% (58 male, 30 females)
Age	44.8±13.1 (18.0, 73.0)
Height (in)	68.4±4.4 (58.0, 76.0)
Weight (lb)	186±42.8 (95.0, 300.0)
Body Mass Index	27.8±4.9 (19.0, 42.0)

Table 2
Follow-up patient information for:
Device is out of the Ureter and Kidney
Device is out of the Body

Follow-Up Visit	Device is out of the Ureter and Kidney	Device is out of the Body
Baseline	0	0
Day 1	9	0
Day 2	7	3
Day 7	22	22
Day 14	24	31
Day 30	14	15
Day 60	4	6
Day 90	0	0
> 90	7	7
Unscheduled visit	0	4

Table 3
Clinical Endpoint Results

Endpoint	Result
Successful placement[1]	98.9% (88/89)*
Study success[2]	78.2% (68/87)
Overall clinical success[3]	94.3% (83/88)
Males with Early Migration	12.1% (7/58)
Females with Early Migration	34.5% (10/29)
Time required to eliminate TUDS from ureter	13.0 (±11.3) days Median = 8 days
Time required to eliminate TUDS from body	21.0 (±17.8) days Median = 15 days
Retained stent fragments at 90 days in renal pelvis	3.4% (3/87)^
Tolerability of TUDS[4] (Moderate to most severe pain)	Day 1: Flank pain – 23.0% (20/87) Urethral pain – 27.9% (24/86) Day 30: Flank pain – 8.7% (7/80) Urethral pain – 2.5% (2/80)
Patient satisfaction[5]	88.8% satisfied (71/80)

* (1) patient required (2) stents

[1] Successful placement of TUDS device

[2] Study success defined as adequate short term drainage defined as the presence of the stent in the ureter and the lack of surgical or other intervention to treat symptoms on the stented side during the first 48 hours following placement.

[3] Alternate Endpoint Defined as adequate drainage with no intervention (regardless of stent presence) and no definitely device-related serious adverse events (SAEs) throughout the 90 day follow-up period.

[4] Tolerability of the TUDS passage through the urinary tract when compared to uretharal discomfort recorded at baseline

[5] Patients rate satisfaction with the stent and with elimination of the stent from the urinary tract

^ Of the 3 patients with retained stent fragments, 2 patients elected to have elective ESWL treatments which were successful and 1 patient declined intervention and is being monitored by her physician. All of these patients were free of retentive symptoms.

The Primary Safety Endpoint: Assessment of adverse events (compared to published clinical studies of plastic ureteral stents), indicated that there were no unanticipated adverse events reported and all adverse events resolved by the end of the study without any permanent sequelae. A list of reported adverse events is presented in Table 4.

Table 4
Reported Adverse Events

Adverse event	Literature range	TUDS study
Flank pain/Loin Discomfort	17 – 50%	12.5% n=11/88 at 1-30 days
Flank pain when voiding	15-54%	0% reported
Hydronephrosis	up to 25%	3.4% n=3/88 at 2, 7 and 90 days
Suprapubic pain/lower abdominal pain	20 – 50%	8% n=7/88 at 1-30 days
Suprapubic pain when voiding	49%	0% reported
Trigonal irritation	19%	0% reported
Urinary frequency	42 – 85%	51.8% n= 44/85 at day 1 49.1% n= 28/57 at day 14
Nocturia	43-56%	0% reported
Urinary urgency	8 – 59%	67% n= 59/88 at baseline 54.8% n= 46/84 at day 1
Dysuria	31-40%	0% reported
Urethral discomfort	-	22.7% n= 20/88 at baseline 27.9% n= 24/86 at day 1 5.3 n= 3/57 at day 14
Incontinence	3%	2.3% n=2/88 at 7 days
Hematuria	40 – 64%	1.1% n=1/88 at day 1
Stent migration	3 – 10%	19.5%* n= 17/87 3.4%* n= 3/87
Stent encrustation	up to 10%	0% reported
Stent/Ureteral Obstruction		2.3% n=2/88 at 2 and 14 days
Stent fracture	0.6%	0% reported
UTI	3 – 35%	2.3% n= 2/88 at 30 days
Bacteriuria	29.9%	0% reported
Additional stent specific procedures	up to 10%	3.4% n=3/88 thru 48 hrs 8.0% n=7/88 thru 90 days
Extravasation	-	0%
Hemorrhage	-	0%
Sepsis	-	0%
Ureteral Reflux	-	0%
Perforation of urinary tract	-	0%
Peritonitis	-	0%
Loss of renal function	-	0%
Stone Formation	-	0%
Urinary Retention	-	0%
Stent fragment retention in renal pelvis-	-	0%

*Even though seventeen (19.5%) of the 87 evaluable patients studied had an early migration of their TUDS device, only three (3.4%) of the 87 evaluable patients needed intervention for symptoms following the stent migration.
Adverse events related to interventions within the first 48 hours;

- 1 patient left flank pain, received IV pain medication
- 1 patient right flank pain, hydronephosis, received IV pain medication
- 1 patient left flank pain, stent repositioned by cystoscopy

Adverse events related to interventions after 48 hours;

- 1 patient left flank pain, ureteroscopy
- 1 patient right distal ureteral obstruction, cystoscopy

Note: By definition, there were no migrations after 48 hours of TUDS indwell (i.e., late migrations) since the stent is expected to degrade and pass out of the ureter after 48 hours.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 8 2002

Ms. Janet A. McGrath
Specialist, Global Regulatory Affairs
Boston Scientific Corporation
Microvasive Urology
One Boston Scientific Place
NATICK MA 01760

Re: K013784
Trade/Device Name: Temporary (dissolvable) Ureteral Drainage Stent (TUDS)
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Product Code: 78 FAD
Regulatory Class: II
Dated: May 30, 2002
Received: May 31, 2002

Dear Ms. McGrath:

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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section I-C. Indications For Use Statement

510(K) Number: K013784

Device Name: Ureteral Stent

Indications For Use:

The proposed device is intended to facilitate the passage of urine from the kidney to the bladder.

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

Prescription Use ✓ Or Over-The-Counter Use ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013784