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510(k) SUMMARY

FEB 2 2 2007

3.1. Submitter

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Date of Preparation of the Summary: August 16th, 2006

3.2. Device Name

A-Device Name-CATHETER

Classification Name: Urological Catheter
Common/Usual Name: Urinary Catheter for Intermittent Use
Proprietary Name: Hi-Slip

B-Device Name-CATHETER

Classification Name: Urological Catheter
Common/Usual Name: Urinary Catheter for Intermittent Use
Proprietary Name: Hi-Slip Plus

C-Device Name-CATHETER

Classification Name: Urological Catheter Kit
Common/Usual Name: Urinary Catheter Kit for Intermittent Use
Proprietary Name: Hi-Slip Kit

3.3. Device Classification

Hi-Slip, Hi-Slip Plus and Hi-Slip Kit all have been classified by the FDA under the heading of **Urological Catheters and Accessories** as a **Class II** device in accordance with the regulations under 21 CFR 876.5130. They are all **Prescription Devices** meaning they can be sold by or on the offer of a physician.

The appropriate panel is **Gastroenterology or Urology** and the Product Code is **GBM/Catheter,Urethral.**

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3.4. Device Description

The **Hi-Slip Hydrophilic Urinary Catheter** is a single use urinary catheter designed for Clean Intermittent Catheterization, drainage of bladder. The device consists of disposable polyvinyl chloride catheter (medical grade PVC) coated with hydrophilic polymer. When the catheter is immersed in water for 30 seconds, it becomes slippery and ready to use. The catheter is provided in a variety of sizes and lengths.

The **Hi-Slip Plus Hydrophilic Urinary Catheter** is a single use urinary catheter designed for Clean Intermittent Catheterization, drainage of bladder. The device consists of disposable PVC (medical grade) catheter coated with hydrophilic polymer and water sachet (sterile water). Coating is activated by the water of integrated water sachet. Water is let down by squeezing the water sachet. When the catheter is immersed in water for 30 seconds, it becomes slippery and ready to use. The PLUS is provided in a variety of sizes and lengths.

Hi-Slip Kit includes a single use coated PVC (medical grade) catheter, urine bag (medical grade PVC urine bag), water sachet (sterile water) and povidone iodine swab for cleaning urethra outlet prior to catheterization. The catheter is coated with a hydrophilic polymer (polyvynil pyrolidone, PVP) which makes the catheter surface slippery when dipped into the water. Patient clean the urethra outlet by using povidone iodine swab and lets the water fill the catheter place in the urine bag by squeezing the sachet. When the catheter is immersed in water for 30 seconds, it becomes slippery and ready to use. Patient disposes the urine directly into urine bag. The KIT is provided in a variety of sizes and lengths.

3.5. Intended Use

Hi-Slip, Hi-Slip Plus and Hi-Slip Kit are all launched for **Clean Intermittent Catheterization-CIC** treatment and indicated for use by patients with **chronic urine retention.** The catheter is inserted into the bladder through the urethra for emptying the bladder.

3.6. Summary of Technological Characteristics/Statement of Substantial Equivalence:

All predicate catheters are single use and intended for single intermittent catheterization.

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The catheter is pre-lubricated with a coating containing polyvinyl pyrrolidone- a kind of hydrophilic polymer (PVP), which binds the water molecules to the surface of the catheter to reduce the risk of friction while inserting the catheter into the urethra.

Hi-Slip is substantially equivalent to the following predicate devices:

- LoFric®Single Use Urinary Catheter K896750, Astra Tech Inc.
- LoFric®Plus Single Use Urinary Catheter K012374, Astra Tech Inc.
- SpeediCath K023254, Coloplast Corp.
- FloaCath Catheter K000070, Rüsch International.

Hi-Slip Plus (with water sachet) is substantially equivalent to the following predicate devices:

- LoFric® Primo Single Use Urinary Catheter K050874, Astra Tech Inc.
- SpeediCath K023254, Coloplast Corp.

Hi-Slip Kit (with urine bag, water sachet and povidone iodine swab) is substantially equivalent to the following predicate devices:

- LoFric®Plus Hydro-Kit II Single Use Urinary Catheter K043241, Astra Tech Inc.
- EasiCath Set K973070, Coloplast Corp. Branded as the SureCath Set in the US.

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3.7. Substantial Equivalence Comparison:

Table 3.1. Hi-Slip-Substantial Equivalence Comparison - General Properties

	Hi-Slip Hydrophilic Urinary Catheter	LoFric® Single Use Urinary Catheter, Astra Tech Inc.	LoFric® Plus Single Use Urinary Catheter, Astra Tech Inc.	SpeediCath Coloplast Corp.
510 (k) number		K896750	K012374	K023254
Device composition	Polyvinyl chloride (PVC) catheter coated with polyvinylpyr rolidone.	Polyvinylchloride (PVC) catheter coated with polyvinylpyr-rolidone and salt.	Polyether block amide catheter coated with polyvinyl-pyrrolidone and salt.	Polyurethane catheter coated with polyvinylpyr-rolidone, placed in a saline solution containing polivinyl-pyrrolidone.
Sizes	Male 40 cm, CH08–24 Female 20 cm, CH08–18 Boys/Pediatric 30 cm, CH06–10 Girls/Pediatric 20 cm, CH06–10 Tiemann 40 cm, CH10–18	Male 40 cm CH 08-24 Female 15 cm CH 08-14 Female 20 cm CH 08-18 Pediatric 20 cm CH06-10 Pediatric 30 cm CH06-10 Tiemann 40 cm CH 10-18	Male 40 cm CH 08-24 Female 20 cm CH 08-18 Pediatric 20 cm CH06-10 Pediatric 30 cm CH06-10 Tiemann 40 cm CH 10-18	Male 40 cm CH08-18 Female 20 cm CH 06-16 Pediatric 20 cm CH 06-10 Tiemann 40 cm CH 10-14

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Table 3.2. Hi-Slip-Substantial Equivalence Comparison: Indications for Use

	Hi-Slip Hydrophilic Urinary Catheter	LoFric® Single Use Urinary Catheter, Astra Tech Inc.	LoFric® Plus Single Use Urinary Catheter, Astra Tech Inc.	SpeediCath Coloplast Corp.
Function of the device	Inserted into the bladder through the urethra for emptying the bladder	Inserted into the bladder through the urethra for emptying the bladder	Inserted into the bladder through the urethra for emptying the bladder	Inserted into the bladder through the urethra for emptying the bladder
Indication for use	Intermittent catheterization (Because of chronic urine retention and other voiding dysfunctions.	Intermittent catheterization	Intermittent catheterization	Chronic urine retention, post-void residual volume (PVR) and voiding dysfunctions.
Features of the device	Hydrophilic coated. Slippery surface. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.
Sterility	Sterile	Sterile	Sterile	Sterile
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack

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Table 3.3. Hi-Slip Plus-Substantial Equivalence Comparison: General Properties

	Hi-Slip Plus Hydrophilic Urinary Catheter	LoFric® Primo Single Use Urinary Catheter, Astra Tech Inc.	SpeediCath Coloplast Corp.
510 (k) number		K050874	K023254
Device composition	Polyvinyl chloride (PVC) catheter coated with polyvinylpyr rolidone and sterile water sachet	Polyvinylchloride (PVC) catheter coated with polyvinylpyr-rolidone and salt and water sachet	Polyurethane catheter coated with polyvinylpyr-rolidone, placed in a saline solution containing polivinyl-pyrrolidone.
Sizes	Male 40 cm, CH08–24 Female 20 cm, CH08–18 Boys/Pediatric 30 cm, CH06–10 Girls/Pediatric 20 cm, CH06–10	Male 40 cm CH 10-18 Female 20 cm CH 08-18 Pediatric 20 cm CH08-10	Male 40 cm CH08-18 Female 20 cm CH 06-16 Pediatric 20 cm CH 06-10 Tiemann 40 cm CH 10-14

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Table 3.4. Hi-Slip Plus-Substantial Equivalence Comparison: Indications for Use

	Hi-Slip Plus Hydrophilic Urinary Catheter	LoFric® Primo Single Use Urinary Catheter, Astra Tech Inc.	SpeediCath Coloplast Corp.
Function of the device	Inserted into the bladder through the urethra for emptying the bladder	Inserted into the bladder through the urethra for emptying the bladder	Inserted into the bladder through the urethra for emptying the bladder
Indication for use	Intermittent catheterization (Because of chronic urine retention and other voiding dysfunctions.	Intermittent catheterization	Chronic urine retention, post-void residual volume (PVR) and voiding dysfunctions.
Features of the device	Hydrophilic coated. Slippery surface. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.
Sterility	Sterile	Sterile	Sterile
Packaging	Peel Pack	Closed PVC	Peel Pack

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Table 3.5 Hi-Slip Kit-Substantial Equivalence Comparison: General Properties:

	Hi-Slip Hydrophilic Urinary Catheter Kit	LoFric® Plus Hydro-Kit II Single Use Urinary Catheter Astratech Inc.	EasiCath Set (identical to the SureCath Set) Coloplast Corp.
510 (k) number		K043241	K973070
Device composition	PVC catheter coated with PVP. Then sterile water sachet povidone iodine swab and the catheter are placed into the urine bag and the bag is sealed.	Polyvinylchloride catheter coated with polyvinylpyr rolidone and salt. Insludes water sachet and urine bag.	Polyvinylchloride catheter coated with polyvinylpyrrolidone, packed with an ampoule with sterile saline solution and sealed in a urine collection bag.
Sizes	Male 08–18 CH Female 08–16 CH Pediatric Girls 06–10 CH Pediatric Boys 06–10 CH Tiemann 10–18 CH	Male CH 08-18 Female CH 08-18 Pediatric CH 06-10 Tiemann CH 10-18	Male CH 08-18 Female CH 08-14 Pediatric CH 06-10

Table 3.6. Hi-Slip Kit-Substantial Equivalence Comparison: Indications for Use

	Hi-Slip Hydrophilic Urinary Catheter Kit	Lofrric Plus Hydro-Kit II Single Use Urinary Catheter Astratech Inc.	EasiCath Set (identical to the SureCath Set) ColoplastCorp
Function of the device	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.
Indication for use	Intermittent catheterization because of chronic urine retention and other voiding dysfunctions.	Chronic urine retention and voiding dysfunctions.	Chronic urine retention and voiding dysfunctions.
Features of the device	Hydrophilic coated. Slippery surface. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.

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Sterilty	Sterile	Sterile	Sterile
Packaging	Peel Pack	Peel Pack	Peel Pack

3.8. Summary of Safety Testing

A summary of the safety testing performed on the coated catheter is listed below.

Table: 3.7 Summary of Safety Tests

Test	Reference	Results
Investigaton of Acute Systemic Toxicity Test	Bioserv Analytik Und Medizinprodukte	Did not cause any acute toxicity, meeting the requirements of ISO 10933-11
Closed Patch Sensitization Test		Did not cause any sensitization, meeting the requirements of DIN ISO 10933-10
Salmonella typhimurium Reverse Mutation Assay		Did not cause any genotoxic activity, meeting the requirements of DIN ISO 10933-3
Cytotoxicity Assay		Caused no toxicological/biological critical cell damages and growth inhibition. Under these conditions the test material is considered non-cytotoxic and meets the requirements of DIN ISO 10993-5 (EN 30993-5)
Skin Irritation Test		Did not cause any irritation under the selected test conditions P.I.O.:0,0., meeting the requirements of DIN ISO 10993-10

Conclusion:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OASIS Medikal Ürünler
c/o Mr. Charles H. Kyper
Kyper & Associates
208 Barrington Overlook
DURHAM NC 27703

FEB 22 2007

Re: K062444
Trade/Device Name: Hi-Slip Single Use Hydrophilic Urinary Catheter
Hi-Slip Plus Single Use Hydrophilic Urinary Catheter with water sachet
Hi-Slip Single Use Hydrophilic Urinary Catheter Kit with water sachet, urine bag and povidone iodine swab
Regulation Number: 21 CFR §876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZD
Dated: January 24, 2007
Received: January 26, 2007

Dear Mr. Kyper:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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.

In addition, we have determined that your device kit contains a povidone iodine swab which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 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, please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David A. Legan

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K062444

Device Name:

Hi-Slip Single Use Hydrophilic Urinary Catheter

Hi-Slip Plus Single Use Hydrophilic Urinary Catheter with water sachet

Hi-Slip Single Use Hydrophilic Urinary Catheter Kit with water sachet, urine bag and povidone iodine swab

Indications for Use:

Hi-Slip, Hi-Slip Plus and Hi-Slip Kit are launched for **Clean Intermittent Catheterization-CIC** treatment and is indicated for use by patients with **chronic urine retention.** The catheter is inserted into the bladder through the urethra for emptying the bladder.

Prescription Use ✓ AND/~~OR~~ **Over-The-Counter Use -**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062444