



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

A Plus International, Incorporated  
C/O Mr. Mark Job  
Third Party Official  
Regulatory Technology Services, LLC  
1394 25<sup>th</sup> Street NW  
Buffalo, Minnesota 55313

JAN 13 2011

Re: K102861  
Trade/Device Name: SurgiPlus Surgical Drapes with AAMI Liquid  
Barrier Level 3 or 4  
Regulation Number: 21 CFR 878.4370  
Regulation Name: Surgical Drape and Drape Accessories  
Regulatory Class: II  
Product Code: KXX  
Dated: January 6, 2011  
Received: January 7, 2011

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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.

Page 2- Mr. Job

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

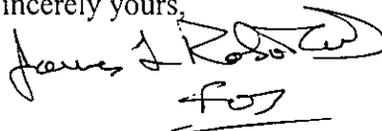
<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Handwritten signature of Anthony D. Watson in black ink, with a horizontal line underneath the signature.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## I. Indications for Use

510(k) Number :   K102861  

**Device Name:** SurgiPlus Surgical Drapes with AAMI Liquid Barrier Level 3 or 4 claim

### **Indications for Use:**

SurgiPlus Surgical Drapes are single use, disposable patient coverings intended to be used by operating room personnel during surgical and other medical procedures as protective covers to isolate surgical incision sites from microbial and other contaminations. Below please find the device names, model numbers and total number of surgical drapes for this submission.

The SurgiPlus Surgical Drapes are also sold as bulk non-sterile, single use items, to repackager/relabeler establishments for further packaging and Ethylene Oxide (EtO) sterilization.

The drapes are classified as Level 3 or Level 4 per AAMI Standard PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health-care facilities.

### **Sterile SurgiPlus SMS Surgical Drape**

No.	Product Code	Product Name	Drape Materials
1	70-1101-S	Laparoscopic Abdominal Drape	SMS base sheet with SPP with PE reinforcement
2	70-1102-S	Laparotomy Drape I, w/Instrument Pad.	SMS base sheet with SPP with PE reinforcement
3	70-1103-S	Transverse Laparotomy Drape II, w/Instrument Pad.	SMS base sheet with SPP with PE reinforcement
4	70-1104-S	Laparoscopic Cholecystectomy Drape, w/Pouches.	SMS base sheet with SPP with PE reinforcement
5	70-1105-S	Chest/Breast Drape, (15"x 10")	SMS base sheet with SPP with PE reinforcement
6	70-2101-S	Cardiovascular Drape (CV)	SMS base sheet with SPP with PE reinforcement
7	70-2102-S	Femoral Angiography Drape	SMS base sheet with SPP with PE reinforcement
8	70-2103-S	Brachial Angiography Drape	SMS base sheet with SPP with PE reinforcement
9	70-3101-S	Cesarean Section with Pouch (C/S)	SMS base sheet with SPP with PE reinforcement
10	70-3102-S	Cesarean Section with Pouch & Fenestration (C/S)	SMS base sheet with SPP with PE reinforcement

A Plus International, Inc.  
SurgiPlus Surgical Drape 510(K) Premarket Submission

No.	Product Code	Product Name	Drape Materials
11	70-3103-S	Obstetrics (OB): Underbuttocks Drape	SMS base sheet
12	70-3104-S	Underbuttocks Drape with Pouch & Port	SMS base sheet with SPP with PE reinforcement
13	70-4101-S	Total Hip Replacement (THR) I, Hip Drape	SMS base sheet with SPP with PE reinforcement
14	70-4102-S	Total Hip Replacement (THR) II, Hip Drape with Pouches	SMS base sheet with SPP with PE reinforcement
15	70-4103-S	Rotator Cuff Repair, Hand Drape (Upper Extremity Drape)	SMS base sheet with SPP with PE reinforcement
16	70-4104-S	Bilateral Limb Drape	SMS base sheet with SPP with PE reinforcement
17	70-4105-S	Beach Chair Shoulder Arthroscopy Drape	SMS base sheet with SPP with PE reinforcement
18	70-4106-S	Shoulder U Pouch	SMS base sheet with SPP with PE reinforcement
19	70-5101-S	Knee Replacement (TKR), Knee Arthroscopy Drape w/Pouch	SMS base sheet with SPP with PE reinforcement
20	70-5102-S	Standard Knee Extremity Drape, (Lower Extremity Drape)	SMS base sheet with SPP with PE reinforcement
21	70-6101-S	Abdominal Total Hysterectomy (ATH)	SMS base sheet with SPP with PE reinforcement
22	70-6102-S	Vaginal Total Hysterectomy (VTH), Laparoscopic Perinea Pack	SMS base sheet with SPP with PE reinforcement
23	70-6103-S	Laparoscopic Assisted Vaginal Hysterectomy (LAVH)	SMS base sheet with SPP with PE reinforcement
24	70-6104-S	Tubal Ligation of Sterilization (T/S), Laparoscopy T-Drape	SMS base sheet with SPP with PE reinforcement
25	70-6105-S	Lithotomy Drape with Pouch	SMS base sheet with SPP with PE reinforcement
26	70-6106-S	Gynaecology set	SMS base sheet with SPP with PE reinforcement
27	70-7101-S	Cystoscopy T Drape	SMS base sheet with SPP with PE reinforcement
28	70-7102-S	Urological Drape	SMS base sheet with SPP with PE reinforcement
29	70-8101-S	Intra Capsular Cataract Extraction (ICCE)	SMS base sheet with SPP with PE reinforcement
30	70-8102-S	Thyroidectomy, Thyroid T-Drape	SMS base sheet with SPP with PE reinforcement
31	70-8103-S	Craniotomy Drape, Head	SMS base sheet with SPP with PE reinforcement
32	70-9101-S	Extremity drape hand, 100x175	SMS base sheet with SPP with PE reinforcement
33	70-9102-S	Extremity drape hand, 150x180	SMS base sheet with SPP with PE reinforcement
34	70-9103-S	Extremity drape hand, 225x300 (3 layers)	SMS base sheet with SPP with PE reinforcement
35	71-3101-S	3/4 sheet	SMS base sheet

K102861

A Plus International, Inc.  
 SurgiPlus Surgical Drape 510(K) Premarket Submission

No.	Product Code	Product Name	Drape Materials
36	71-3102-S	1/2 sheet	SMS base sheet
37	71-3103-S	Top drape	SMS base sheet with SPP with PE reinforcement
38	71-3104-S	Side drape	SMS base sheet with SPP with PE reinforcement
39	71-3105-S	Bottom Drape	SMS base sheet with SPP with PE reinforcement

**Non-Sterile SurgiPlus SMS Surgical Drape**

No.	Product Code	Product Name	Drape Materials
1	70-1101-B	Laparoscopic Abdominal Drape	SMS base sheet with SPP with PE reinforcement
2	70-1102-B	Laparotomy Drape I, w/Instrument Pad.	SMS base sheet with SPP with PE reinforcement
3	70-1103-B	Transverse Laparotomy Drape II, w/Instrument Pad.	SMS base sheet with SPP with PE reinforcement
4	70-1104-B	Laparoscopic Cholecystectomy Drape, w/Pouches.	SMS base sheet with SPP with PE reinforcement
5	70-1105-B	Chest/Breast Drape, (15"x 10")	SMS base sheet with SPP with PE reinforcement
6	70-2101-B	Cardiovascular Drape (CV)	SMS base sheet with SPP with PE reinforcement
7	70-2102-B	Femoral Angiography Drape	SMS base sheet with SPP with PE reinforcement
8	70-2103-B	Brachial Angiography Drape	SMS base sheet with SPP with PE reinforcement
9	70-3101-B	Cesarean Section with Pouch (C/S)	SMS base sheet with SPP with PE reinforcement
10	70-3102-B	Cesarean Section with Pouch & Fenestration (C/S)	SMS base sheet with SPP with PE reinforcement
11	70-3103-B	Obstetrics (OB): Underbuttocks Drape	SMS base sheet
12	70-3104-B	Underbuttocks Drape with Pouch & Port	SMS base sheet with SPP with PE reinforcement
13	70-4101-B	Total Hip Replacement (THR) I, Hip Drape	SMS base sheet with SPP with PE reinforcement
14	70-4102-B	Total Hip Replacement (THR) II, Hip Drape with Pouches	SMS base sheet with SPP with PE reinforcement
15	70-4103-B	Rotator Cuff Repair, Hand Drape (Upper Extremity Drape)	SMS base sheet with SPP with PE reinforcement
16	70-4104-B	Bilateral Limb Drape	SMS base sheet with SPP with PE reinforcement
17	70-4105-B	Beach Chair Shoulder Arthroscopy Drape	SMS base sheet with SPP with PE reinforcement
18	70-4106-B	Shoulder U Pouch	SMS base sheet with SPP with PE reinforcement
19	70-5101-B	Knee Replacement (TKR), Knee Arthroscopy Drape w/Pouch	SMS base sheet with SPP with PE reinforcement

A Plus International, Inc.  
SurgiPlus Surgical Drape 510(K) Premarket Submission

No.	Product Code	Product Name	Drape Materials
20	70-5102-B	Standard Knee Extremity Drape, (Lower Extremity Drape)	SMS base sheet with SPP with PE reinforcement
21	70-6101-B	Abdominal Total Hysterectomy (ATH)	SMS base sheet with SPP with PE reinforcement
22	70-6102-B	Vaginal Total Hysterectomy (VTH), Laparoscopic Perinea Pack	SMS base sheet with SPP with PE reinforcement
23	70-6103-B	Laparoscopic Assisted Vaginal Hysterectomy (LAVH)	SMS base sheet with SPP with PE reinforcement
24	70-6104-B	Tubal Ligation of Sterilization (T/S), Laparoscopy T-Drape	SMS base sheet with SPP with PE reinforcement
25	70-6105-B	Lithotomy Drape with Pouch	SMS base sheet with SPP with PE reinforcement
26	70-6106-B	Gynaecology set	SMS base sheet with SPP with PE reinforcement
27	70-7101-B	Cystoscopy T Drape	SMS base sheet with SPP with PE reinforcement
28	70-7102-B	Urological Drape	SMS base sheet with SPP with PE reinforcement
29	70-8101-B	Intra Capsular Cataract Extraction (ICCE)	SMS base sheet with SPP with PE reinforcement
30	70-8102-B	Thyroidectomy, Thyroid T-Drape	SMS base sheet with SPP with PE reinforcement
31	70-8103-B	Craniotomy Drape, Head	SMS base sheet with SPP with PE reinforcement
32	70-9101-B	Extremity drape hand, 100x175	SMS base sheet with SPP with PE reinforcement
33	70-9102-B	Extremity drape hand, 150x180	SMS base sheet with SPP with PE reinforcement
34	70-9103-B	Extremity drape hand, 225x300 (3 layers)	SMS base sheet with SPP with PE reinforcement
35	71-3101-B	3/4 sheet	SMS base sheet
36	71-3102-B	1/2 sheet	SMS base sheet
37	71-3103-B	Top drape	SMS base sheet with SPP with PE reinforcement
38	71-3104-B	Side drape	SMS base sheet with SPP with PE reinforcement
39	71-3105-B	Bottom Drape	SMS base sheet with SPP with PE reinforcement

**Caution:**

The contents of this package, as with any woven/nonwoven material, may burn if exposed to a flame or an extremely hot object. Avoid contact with an open flame or high intensity heat sources. Do not use in the presence of flammable anesthesia.

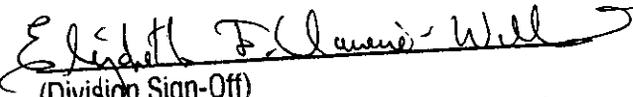
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Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use  X   
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:  K102861