PolyConversions, Inc.
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VR® Protective Wear

PolyConversions, Inc. located at 3202 Apollo Drive in Champaign, Illinois is a Class 1 registered facility with the Food & Drug Administration specializing in the manufacturing of personal protective equipment. Our VR® personal protective gowns have previously passed the following testing methods conducted in May 2020:

- Water Resistance: Impact Penetration Test
- ASTM F 1670/F 1670M – 17a Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- Water Resistance: Hydrostatic Pressure Test

In response to market demand, PolyConversions, Inc. has completed testing of our multi-purpose VR® personal protective gowns, commonly used in sterile processing, against baseline chemotherapy drug resistance on November 6, 2020. Baseline chemotherapy drugs used in this testing are as follows:

- Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)
- Cisplatin, 1.0 mg/ml (1,000 ppm)
- Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)
- Dacarbazine, 10.0 mg/ml (10,000 ppm)
- Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)
- Etoposide, 20.0 mg/ml (20,000 ppm)
- Fluorouracil, 50.0 mg/ml (50,000 ppm)
- Mitomycin C, 0.5 mg/ml (500 ppm)
- Paclitaxel, 6.0 mg/ml (6,000 ppm)
- ThioTepa, 10.0 mg/ml (10,000 ppm)
- Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)

In conducting a risk-based assessment, PolyConversions, Inc. has determined that the testing of our VR® personal protective gowns against baseline chemotherapy drug resistance does not significantly affect the safety of the user or the effectiveness of the device.

In completing this testing, PolyConversions, Inc. maintains that the indications of use our VR® personal protective gowns are a minimal/low barrier protectant designed to keep the user (healthcare professionals) safe during the preparation and administration of chemotherapy drugs in healthcare settings and makes no protection claims beyond the scope of AAMI levels 1 & 2. PolyConversions, Inc. also makes no claims of patient protection in the use of our VR® personal protective gowns and does not label this device for patient use.

Additionally, PolyConversions, Inc. has assessed the performance and risks associated with the use of our VR® personal protective gowns and has determined there to be no change in how the device

functions in the preparation and administration of chemotherapy drugs. PolyConversions, Inc. makes no claims of device reusability and maintains the device to be single use only.

PolyConversions, Inc.'s VR® personal protective gowns are sold through our various distribution partners into healthcare facilities for use by healthcare professionals and do not require a prescription (Rx) to obtain nor are they sold over the counter (OTC) by retailers. This section of Flowchart A referencing labeling changes is not applicable.

PolyConversions, Inc.'s VR® personal protective gowns will not prompt any changes to the device name or description consistent with the indications for use. This change is to provide clarity that these gowns, although already a multi-purpose device, have now been tested successfully against baseline chemotherapy drug resistance and does not significantly affect the safety of the user or effectiveness of the aforementioned device.

PolyConversions, Inc.'s VR® personal protective gowns are not designed nor intended for use in the diagnosis, treatment, prevention, curing or mitigation of any new types of diseases, conditions, or any variations in patient population. VR® personal protective gowns only provide minimal/low barrier protection to end users preparing and administering chemotherapy drugs.

In examining all areas of Flowchart A referencing labeling changes, no new risks or significantly modified existing risks have presented themselves to prompt submission of a 510(k) with the Food & Drug Administration.

Given consideration of all the above factors, in correlation with Flowchart A referencing labeling changes, PolyConversions, Inc. has concluded that this decision, based on the labeling change alone, classifies as documentation. This change in labeling is in response to VR® personal protective gowns now being marketed and sold into cancer treatment facilities. Due to the changes only being to the labeling, the content of the labeling is not changed, which does not alter the indications for use statement and does not affect the directions for use.

PolyConversions, Inc. has elected not to file 510(k) with the Food & Drug Administration based on the assessment and history of VR® personal protective gowns. Historically, there has been no relationship between hazard and harm with this device with the likelihood or probability of occurrence being extremely low to none. Additionally, this device has not undergone any significant design alterations or modifications that would compromise the safety or effectiveness of the device and has not carried any previous applicable regulatory history, including 510(k) clearances and comparison of modified device to the most recently cleared version.

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Regulatory Change Assessment

Product Name: VR® Gowns

Date of Assessment: 12/31/20 & 1/2/21

Device Description: VR® Gowns are a minimal/low barrier protectant designed to keep the user safe during the preparation and administration of chemotherapy drugs in healthcare settings.

Description of Change(s): Change in labeling as VR® Gowns have been successfully tested against baseline chemotherapy drug resistance.

Reason for Change(s): VR® Gowns are now being marketed and sold into cancer treatment facilities.

Applicable Regulatory History (including 510(k) #s and comparison of modified device to most recently cleared version): Non-applicable.

Completed Checklist Attached: No. Changes are to the labeling of the device. The content of the labeling is not changed, which does not alter the indications for use statement and does not affect the directions for use. Submission of a new 510(k) is not required.

Recommended Regulatory Action: Letter to file in accordance to FDA's Deciding When to Submit a 510(k) for a Change to an Existing Device guidance.

Supporting Documents: Risk-Based assessment in accordance with Flowchart A referencing label changes in FDA's Deciding When to Submit a 510(k) for a Change to an Existing Device guidance.

Signature(s): Justin W. DeAtley, Quality Assurance Coordinator