PolyConversions, Inc.
505 Condit Drive
Rantoul, IL 61866
Phone: 217-893-3330
Fax: 217-893-3003
www.PolyCoUSA.com
email: info@PolyCoUSA.com

PolyCo
innovative protective solutions

January 1, 2019

RE: FDA Compliance of PolyWear® and VR® Personal Protective Wear

To Whom It May Concern:

PolyConversions, Inc. manufactures personal protective wear that under criteria established by FDA is classified as Class I and therefore in accordance with FDA's 65 FR 2318 (January 14, 2000), a rule change, is exempt from 510(k) premarket notification.

Specifically, the classification regulation was changed in 2000 to read;

21 CFR 878.4040 Surgical apparel.

(a) Identification. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) Classification. (1) Class II (special controls) for surgical gowns and surgical masks. (2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9.

Since PolyConversions, Inc. does not market, make claims or describes its personal protective wear for use in Surgery, the Company considers its personal protective wear as Class 1 devices exempt from FDA premarket notification.

PolyConvesions, Inc. has listed their PolyWear® and VR® products marketed as Class I devices in their FDA Medical Device Establishment Registration (Number: 1423205).

Sincerely,

Ronald N. Smith
President