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510(k) Summary

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OREX Surgeon's Vest

Legally marketed equivalent device: Surgeon's Vest
Isolyser/White Knight

Material: OREX nonwoven fabric

Description of Device: A surgeon's vest constructed of OREX nonwoven fabric for use as additional protection for surgeons during a surgical procedure. The material is flame resistant, and is resistant to fluid penetration. The material also has low lint characteristics, meets suitable strength requirements for its intended use, and is resistant to tearing. The material is dissolvable after use in an OREX processor or may be disposed of using the hospital or healthcare facilities standard disposal method.

All testing conducted on the fabric used in this product was tested according to guidance documents published for biocompatibility. The results from these tests were found to be acceptable when compared to that of the predicate device. In some instances test results were found to exceed those of the predicate device. Through these test results determination has been established that this device and the predicate device are similar in use and functionality.