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510(k) SUMMARY (K964114)

NAME OF FIRM: DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

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TRADE NAME: DePuy Opti-Con and E-Z Shield Systems

COMMON NAME: Surgical faceshields

CLASSIFICATION: 878.4040 Surgical apparel

DEVICE PRODUCT CODE: 79 FXX

SUBSTANTIALLY EQUIVALENT DEVICES:

- Splash Shield Splash Shields
- DePuy Disposable Filter/Hood
- DePuy Shades™ Protective Glasses

INTENDED USE:

The DePuy Opti-Con and E-Z Shield Systems are intended as face shields to be worn by operating room personnel during surgical procedures to provide splash protection to protect the operating room personnel from the transfer of microorganisms, body fluids and particulate material. The Opti-Con Shields, E-Z Shield and Opti-Con goggles are intended to be disposable. The Opti-Con head gear is intended to be re-usable.

DEVICE DESCRIPTIONS AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The Opti-Con Faceshield System consists of a disposable faceshield which is designed to provide splash protection to the wearer's eyes, nose, mouth and ears during surgical procedures and re-usable headgear which fits over the top of the head and holds the faceshield in place. The disposable faceshields are manufactured from polycarbonate and are available in a standard and a long length, either sterile or non-sterile. The Opti-Con Faceshields are substantially equivalent to the Splash Shield Splash Shields in that they have similar designs and the same intended use. Impact testing of both designs demonstrates that the impact resistance of the Opti-Con Shields is greater than that of the Splash Shield Splash Shields.

The E-Z Shield is a one-piece disposable faceshield and headband which is also designed to provide splash protection to the wearer's eyes, nose, mouth and ears during surgical procedures. The E-Z Shield is identical to the Splash Shield Splash Shield but is relabeled by DePuy. The E-Z Shield is manufactured from PETG as is the faceshield of the DePuy Disposable Filter/Hood.

The Opti-Con goggles are disposable goggles designed to protect the eyes during surgical procedures. They are substantially equivalent to the DePuy Shades Protective Glasses in that they have similar designs, the same intended use, and both are manufactured from polycarbonate.