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XIV. SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ULTRAFREE STERILE LATEX POWDER-FREE SURGICAL GLOVES

Manufacturer:	Allegiance Healthcare Sdn. Bhd. Plot 87 Kampung Jawa 11900 Bayan Lepas Penang, West Malaysia
Regulatory Affairs Contact:	Maryalice Smith Allegiance Healthcare Corporation 1500 Waukegan Road, Bldg. K McGaw Park, IL 60085
Telephone:	(847) 785-3322
Date Summary Prepared:	February, 1997
Product Trade Name:	Ultrafree Sterile Latex Powder-Free Surgical Gloves
Common Name:	Surgical Glove
Classification:	Glove, Surgical
Predicate Devices:	Triflex® Sterile Latex Powder-Free Surgical Gloves
Description:	The Ultrafree Surgical gloves are formulated using natural rubber latex and offered sterile.
Intended Use:	Ultrafree Sterile Latex Powder-Free Surgical Gloves are intended for use in sterile environments within hospitals and other healthcare facilities. The gloves are appropriate for use during invasive surgical procedures and non-invasive medical procedures requiring sterility. They are intended to be worn by operating room personnel to protect a surgical wound from contamination.

Substantial Equivalence: The Ultrafree Sterile Latex Powder-Free Surgical Gloves are substantially equivalent to Triflex® Sterile Latex Powder-Free Surgical Gloves in that they provide the following characteristics:

- intended use
- size, configuration, packaging
- made of natural rubber latex
- tensile strength and thickness profiles

Summary of Testing:

Test	Result
Primary Skin Irritation	Glove does not display any potential for irritation.
Systemic Toxicity	Glove does not elicit any toxic reactions to acute application.
Intracutaneous Reactivity	No reactivity was observed.
Hemocompatibility	Gloves are hemocompatible exhibiting no lysis.
Guinea Pig Maximization	Glove does not display any potential for irritation.
Ultimate Elongation & Tensile Strength	Glove meets or exceeds requirements for rubber surgical gloves per ASTM D3577-91.
Barrier Defects	Glove meets or exceeds requirements per 21 CFR §800.20, AQL = 2.5.
Data/Test Method	Glove meets powder level requirements for "Powder Free" designation using the vacuum filtration method plus a negative iodine test. Results generated values below the 2 mg/glove cornstarch level including negative iodine test.