

SEP 20 1996

510(k) Summary

MAXXUS* POWDER FREE ORTHOPAEDIC LATEX SURGICAL GLOVES

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K962986

Submitter's Name:	Johnson & Johnson Medical Inc.
Submitter's Address:	2500 Arbrook Blvd. Arlington, Texas 76014
Submitter's Phone Number:	(817) 784-4897
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Name of Contact Person:	Margaret Marsh
Date of Preparation:	September 17, 1996
Name of Device:	
Trade Name:	MAXXUS* Powder Free Orthopaedic Latex Surgical Gloves
Common Name:	Surgical Gloves
Classification Name:	Surgeon's Gloves
Legally Marketed Device to Which Equivalency Is Being Claimed:	MAXXUS Powder Free Orthopaedic Latex Surgical Gloves as described in this 510(k) notification are substantially equivalent to the currently marketed MAXXUS Orthopaedic Latex Surgical Gloves. The manufacturing differences between the two products consist of additional steps needed to render the gloves powder free.
Description of the Device:	MAXXUS Powder Free Orthopaedic Latex Surgical Gloves meet the description of Rubber Surgical Gloves as described in American Society for Testing Materials (ASTM D 3577-91) as Type 1 gloves compounded primarily from rubber latex. They are brown in color and are non-powdered. They are packaged sterile in pairs in sizes 5-1/2 through 9.

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Intended Use of the Device:	MAXXUS Powder Free Orthopaedic Latex Surgical Gloves are Intended to protect the wearer from liquids such as body fluids and blood, as well as to protect surgical wounds or sterile fields from microbiological contamination from the wearer.
Summary of Technological Characteristics Compared to the Predicate Device:	The current notification describes minor modifications to the manufacturing process which allow for a powder free product.
Brief Discussion of Nonclinical Tests:	<p>Testing performed per ASTM D-3577-91 and 21 CFR 800.20 indicates that the product meets the requirements of these standards.</p> <p>Primary skin irritation testing in the rabbit and delayed contact sensitization testing in the guinea pig indicate no irritation or sensitization.</p> <p>Final product is negative for the presence of starch using the USP Iodine test.</p>
Brief Discussion of Clinical Tests:	No new clinical tests were conducted under this 510(k).
Conclusions Drawn for the Nonclinical and Clinical Tests:	Nonclinical laboratory and animal data indicate that the powder free product meets all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA:	Not applicable

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