

K965055 Nitra-Touch™

**Checklist
Section 21.0**

- [1] 510 (k) Summary
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APR 22 1997

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- [3] Trade Name: Nitra-Touch™
Common Name: Exam Gloves
Classification Name: Patient Examination Glove
- [4] Nitra-Touch™ examination gloves, meet all of the requirements of ASTM D 3578 with the following variation.
- [5] Nitra-Touch™ examination gloves meet all the current specifications for ASTM D 3578 Rubber Examination Gloves except for the ultimate elongation percentage before and after aging.
- [6] Nitra-Touch™ examination gloves are disposable device intended for medical purposes that is worn on the examiners hand to prevent contamination between patient and examiner.
- [7] Nitra-Touch™ examination gloves are summarized with the following technological characteristics compared to ASTM or equivalent standards.

Characteristics	Standard
Dimensions	Meets ASTM D 3578
Physical Properties	Meets ASTM D 3578
Except Ultimate Elongation meets specifications described under Attachment II	Original Ultimate Elongation 500% minimum Aged Ultimate Elongation 400% minimum

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Nitra-Touch™

Freedom from holes

Meets ASTM D 3578
Meets ASTM D 5151

Powder-Free

Meets described test in Attachment V

Not more than 2 mg residue by mass.

Tensile Strength 60% higher than vinyl (synthetic) examination gloves

Tensile Strength MPa
ASTM D 5250
ASTM D 3578
Vinyl = 10.5
Nitra-Touch™ = 17.1

Puncture resistance of Nitra-Touch™ is eight (8) times greater than vinyl and nearly twice that of competitive nitrile gloves

Puncture lbf/in
ASTM D 120-87
Nitra-Touch™ = 1625
Blue Nitrile = 929
Vinyl (Synthetic) = 184

Nitrile film provides excellent chemical resistance to glutaraldehyde.

Glutaraldehyde Resistance
ASTM T F739-91
Source: TRI/Environmental, Inc.
Breakthrough Time = >480
Permeation Rate = <0.013 $\mu\text{g}/\text{cm}^2 \text{ min}$

Biocompatibility

Primary Skin Irritation in Rabbits
Guinea Pig Sensitization

Passes
Passes

- [8] The performance test data of the non clinical tests are the same as mentioned immediately above.
- [9] Clinical data is not needed for medical gloves or for most devices cleared by the 510(k) process.
- [10] It is concluded that Nitra-Touch™ examination gloves are as safe, as effective, and perform as well as the glove performance standards referenced in Section 7 above and therefore meet:

ASTM listed standards,
FDA hole requirements, and
labeling claims for the product.

- [11] This summary will include any other information reasonably deemed necessary by The FDA.

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