FDA

Product Classification
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Device	Vinyl Patient Examination Glove
Regulation Description	Non-powdered patient examination glove.
Definition	A vinyl patient examination glove is a disposable device made of poly(vinyl chloride) that may or may not bear a trace amount of residual powder, and is intended to be worn on the hand for medical purposes to provide a barrier against potentially infectious materials and other contaminants.
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	LYZ
Premarket Review	[Surgical and Infection Control Devices](6) (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(k)
Regulation Number	[880.6250](7)
Device Class	1
Total Product Life Cycle (TPLC)	[TPLC Product Code Report](8)
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Recognized Consensus Standards

- 5-62 ANSI ASQ Z1.4-2003 (R2018)
  [Sampling Procedures and Tables for Inspection by Attributes](9)
- 6-145 ASTM D3578-05 (Reapproved 2015)
  [Standard Specification for Rubber Examination Gloves](10)
- 6-147 ASTM D6978-05 (Reapproved 2019)
  [Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs](11)
- 6-176 ASTM D7103-06 (Reapproved 2013)
  [Standard Guide for Assessment of Medical Gloves](12)
- 6-178 ASTM D6124-06 (Reapproved 2017)
  [Standard Test Method for Residual Powder on Medical Gloves](13)
- 6-183 ASTM D5250-06 (Reapproved 2015)
  [Standard Specification for Poly(vinyl chloride) Gloves for Medical Application](14)
- 6-354 ASTM D7907-14 (Reapproved 2019)
  [Standard Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves](15)
- 6-401 ASTM D7160-16
  [Standard Practice for Determination of Expiration Dating for Medical Gloves](16)
- 6-424 ASTM D5151-19
  [Standard Test Method for Detection of Holes in Medical Gloves](17)
- 6-440 ASTM D3578-19
  [Standard Specification for Rubber Examination Gloves](18)
- 6-444 ASTM D7103-19
  [Standard Guide for Assessment of Medical Gloves](19)
- 6-445 ASTM D5250-19
  [Standard Specification for Poly(vinyl chloride) Gloves for Medical Application](20)

Implanted Device?	No
Life-Sustain/Support Device?	No

Third Party Review

- Eligible for *[Accredited Persons Program](21)*

Accredited Persons

- [Accelerated Device Approval Services](22)
- [Center For Measurement Standards Of Industrial](23)
- [Global Quality And Regulatory Services](24)
- [Regulatory Technology Services, Llc](25)
- [Sgs North America](26)
- [Third Party Review Group, Llc](27)

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