FDA 510(k) Premarket Notification

CLEARED

Oct 3, 2002
41 days to decision

K022808 DERMAGRIP POWDER FREE LATEX EXAMINATION GLOVES, NON-STERILE WITH PROTEIN CONTENT LABELING CLAIM (50 UG OR LESS)

K022808 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k022808/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 23, 2002
Decision date	Oct 3, 2002
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Wrp Specialty Products Sdn. Bhd.**
Location	Selangor Daurl Ehsan, Sepang, MY
Contact	V. NADARAJAN
510(k) history	18 submissions · 18 cleared · 1999-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k022808/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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