

K982716 OMNIGRACE LATEX EXAMINATION GLOVE, POWDER-FREE, WITH PROTEIN CLAIM

Nov 30, 1998
118 days to decision

K982716 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k982716/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 4, 1998
Decision date	Nov 30, 1998
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Omnigrace (Thailand) , Ltd.
Location	North Canton, OH, US
Contact	K.C. CHOONG
510(k) history	12 submissions · 12 cleared · 1998-2001

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Device record: <https://www.510kdatabase.net/k982716/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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