FDA 510(k) Premarket Notification

K991846 PATIENT EXAMINATION GLOVE, NITRILE, POWDERED, TURQUOISE, NON-STERILE

CLEARED

Aug 5, 1999
69 days to decision

K991846 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k991846/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	May 28, 1999
Decision date	Aug 5, 1999
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omnigrace , Ltd.**
Location	Canton, OH, US
Contact	K.C. CHOONG
510(k) history	8 submissions · 8 cleared · 1997-2000