FDA 510(k) Premarket Notification

K990499 PREPOWDERED NITRILE EXAMINATION GLOVES

CLEARED

Apr 2, 1999
44 days to decision

K990499 · Product code: **LZA** · General Hospital
Source: https://www.510kdatabase.net/k990499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Feb 17, 1999
Decision date	Apr 2, 1999
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Flexitech Sdn. Bhd.**
Location	Klang, Selangor, MY
Contact	KENNY H. N. LIEW
510(k) history	6 submissions · 6 cleared · 1999-2000