

K963866 AMBIDERM (WHITE POW LATEX EXAM GLOVES W/ PROTEIN)

Feb 10, 1997
210 days to decision

K963866 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k963866/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Jul 15, 1996
Decision date	Feb 10, 1997
Days to decision	210 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Supertex Industrial, S.A. DE C.V.
Location	Zapopan, Jalisco, MX
Contact	JAMES F LOGAN
510(k) history	3 submissions · 3 cleared · 1997-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k963866/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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