FDA 510(k) Premarket Notification

K010919 MALE NATURAL RUBBER LATEX CONDOM

CLEARED

Jun 15, 2001
80 days to decision

K010919 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k010919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Mar 27, 2001
Decision date	Jun 15, 2001
Days to decision	80 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Innolatex Sdn. Bhd**
Location	Shah Alam,Selangor Darul Ehsan, MY
Contact	CHANG AH-KAU
510(k) history	9 submissions · 9 cleared · 2000-2006