FDA 510(k) Premarket Notification

K070511 RICHTER MALE LATEX CONDOM

CLEARED

Jan 14, 2008
326 days to decision

K070511 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k070511/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Feb 22, 2007
Decision date	Jan 14, 2008
Days to decision	326 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Richter Rubber Technology Sbn Bhd**
Location	Durham, NC, US
Contact	SUBRAMANIAM NARAYANASAMY
510(k) history	1 submissions · 1 cleared · 2008-2008