FDA 510(k) Premarket Notification

K980019 HTL MALE CONDOM

CLEARED

Apr 1, 1998
89 days to decision

K980019 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k980019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Jan 2, 1998
Decision date	Apr 1, 1998
Days to decision	89 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Reddy Medtech Health Products , Ltd.**
Location	Plainsboro, NJ, US
Contact	A.V.K. REDDY
510(k) history	4 submissions · 4 cleared · 1998-1998