FDA 510(k) Premarket Notification

K203536 Male Latex Condom

CLEARED

Sep 3, 2021
274 days to decision

K203536 · Product code: **HIS** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k203536/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Condom (HIS)
Date received	Dec 3, 2020
Decision date	Sep 3, 2021
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Global Protection Corp.**
Location	Boston, MA, US
Contact	Christina Cataldo
510(k) history	11 submissions · 10 cleared · 1997-2025