FDA 510(k) Premarket Notification

K910254 DIAGNOSTIC HYSTEROSCOPY REDIKIT (TM)

CLEARED

Apr 18, 1991
86 days to decision

K910254 · Product code: **HHE** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k910254/

SUBMISSION DETAILS

Decision	Substantially Equivalent - SD
Submission type	Traditional
Device classification	Cup, Menstrual (HHE)
Date received	Jan 22, 1991
Decision date	Apr 18, 1991
Days to decision	86 days
Third-party review	No

APPLICANT

Company	**CooperSurgical, Inc.**
Location	Mountain View, CA, US
Contact	CHARLES L ROSE
510(k) history	41 submissions · 40 cleared · 1991-2025