FDA 510(k) Premarket Notification

K943558 PRO'TECT

CLEARED

May 24, 1995
306 days to decision

K943558 · Product code: **KPN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k943558/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alarm, Conditioned Response Enuresis (KPN)
Date received	Jul 22, 1994
Decision date	May 24, 1995
Days to decision	306 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Health Sense Intl., Inc.**
Location	Coos Bay, OR, US
Contact	HOWARD M HOLSTEIN
510(k) history	4 submissions · 4 cleared · 1991-1996