K924935 HARD TISSUE REPLACE(HTR(R))-PATIENT-MATCH IMPLANT

CLEARED

Sep 2, 1993
337 days to decision

K924935 · Product code: **KKY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k924935/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Sep 30, 1992
Decision date	Sep 2, 1993
Days to decision	337 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Polyclinic Medical Center**
Location	Mchenry, IL, US
Contact	MARY L VERSTYNEN
510(k) history	2 submissions · 2 cleared · 1983-1993