

**K924935 HARD TISSUE REPLACE(HTR(R))-PATIENT-MATCH  
IMPLANT**Sep 2, 1993  
337 days to decisionK924935 · Product code: **KKY** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k924935/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924935/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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