

K934861 HARD TISSUE REPLACEMENT (HTR) GRANULARNov 4, 1994
388 days to decisionK934861 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k934861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Oct 12, 1993
Decision date	Nov 4, 1994
Days to decision	388 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Poly-Medics, Inc.
Location	Warsaw, IN, US
Contact	MARY L VERSTYNEN
510(k) history	5 submissions · 1 cleared · 1994-1996

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