

**K080507 AOC POROUS POLYETHYLENE, AOC POROUS HDPE,
AOC POROUS POLYETHYLENE SURGICAL IMPLANT**Apr 21, 2008
56 days to decisionK080507 · Product code: **KKY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k080507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Polytetrafluoroethylene Vitreous Carbon, For Maxillofacial Reconstruction (KKY)
Date received	Feb 25, 2008
Decision date	Apr 21, 2008
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ceremed , Inc.
Location	Los Angeles, CA, US
Contact	TADEUSZ WELLISZ
510(k) history	20 submissions · 20 cleared · 2004-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080507/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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