

**K121795 CALCIUM HYDROXYLAPATITE VOCAL FOLD  
IMPLANT**Feb 22, 2013  
248 days to decisionK121795 · Product code: **MIX** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k121795/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Vocal Cord Medialization (MIX)
Date received	Jun 19, 2012
Decision date	Feb 22, 2013
Days to decision	248 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Cytophil, Inc.</b>
Location	Whitefish Bay, WI, US
Contact	BILL HUBBARD
510(k) history	8 submissions · 8 cleared · 2008-2015

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121795/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026