

**K970519 UNITRON MODEL SOUND F/X PROGRAMMABLE ITE
(SF/X PROGRAMMABLE)**Apr 24, 1997
72 days to decisionK970519 · Product code: **ESD** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k970519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Feb 11, 1997
Decision date	Apr 24, 1997
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Unitron Industries, Inc.
Location	Mchenry, IL, US
Contact	JERRY G JOHNSON
510(k) history	69 submissions · 69 cleared · 1976-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970519/> 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 July 5, 2026