

**K014168 AU6 (TECHNOS/TECHNOS MP) ULTRASOUND
IMAGING SYSTEM (ADDITION OF 3D IMAGING MODE AND
MUSCULOSKELETAL INDICATION)**Apr 25, 2002
127 days to decisionK014168 · Product code: **IYN** · Radiology
Source: <https://www.510kdatabase.net/k014168/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Doppler, Ultrasonic (IYN)
Date received	Dec 19, 2001
Decision date	Apr 25, 2002
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosound Esaote, Inc.
Location	Indianapolis, IN, US
Contact	COLLEEN H DENSMORE
510(k) history	20 submissions · 20 cleared · 1997-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014168/>; 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 19, 2026