

**K040195 CALYSTO IMAGE IV-IMAGE AND INFORMATION
MANAGEMENT SYSTEM**Apr 7, 2004
70 days to decisionK040195 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k040195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 28, 2004
Decision date	Apr 7, 2004
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Witt Biomedical Corp
Location	Melbourne, FL, US
Contact	ELFRIEDE PAGAN
510(k) history	5 submissions · 5 cleared · 2004-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040195/> 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