

K991446 BIOSACA SYSTEM, MODEL 800Jul 23, 1999
88 days to decisionK991446 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k991446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Apr 26, 1999
Decision date	Jul 23, 1999
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosys AB (Publ)
Location	Chester, NY, US
Contact	JANE B CAMPBELL
510(k) history	2 submissions · 2 cleared · 1999-1999

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