

K013401 K-SYSTEMS CULTURE BAG SEALER AND CULTURE BAGS TYPE CBS-1 AND CB-01Dec 14, 2001
60 days to decisionK013401 · Product code: **MQG** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k013401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessory, Assisted Reproduction (MQG)
Date received	Oct 15, 2001
Decision date	Dec 14, 2001
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	K-Systems, Kivex Biotec , Ltd.
Location	Birkerod, DK
Contact	JACOB MOLLENBACH
510(k) history	1 submissions · 1 cleared · 2001-2001

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