

K183088 ADVIA Centaur Erythropoietin (EPO) assayAug 2, 2019
269 days to decisionK183088 · Product code: **GGT** · Hematology
Source: <https://www.510kdatabase.net/k183088/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythropoietin (GGT)
Date received	Nov 6, 2018
Decision date	Aug 2, 2019
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Axis-Shield Diagnostics Limited
Location	Dundee, GB
Contact	Claire Dora
510(k) history	4 submissions · 4 cleared · 2016-2019

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