

K133940 OXFORD FIXED LATERAL BEARING PARTIAL KNEE REPLACEMENT (BEARINGS / TRAYS)Mar 28, 2014
95 days to decisionK133940 · Product code: HRY · Orthopedic
Source: <https://www.510kdatabase.net/k133940/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Semi-constrained, Cemented, Metal/polymer (HRY)
Date received	Dec 23, 2013
Decision date	Mar 28, 2014
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomet UK, Ltd.
Location	Warsaw, IN, US
Contact	JASON HECKAMAN
Website	http://www.biomet.co.uk/
510(k) history	3 submissions · 3 cleared · 2014-2020

Biomet UK, Ltd. is an orthopedic device manufacturer with a registered facility in Warsaw, US. Now part of Zimmer Biomet, the brand continues to operate under the parent company's global musculoskeletal platform. The company has received FDA 510(k) clearances from total submissions. All submissions focused on orthopedic devices, with clearances spanning 2014 to 2020. The company is currently inactive, with no new clearances recorded in the past five years. Historical cleared devices include ceramic femoral heads and partial knee replacement bearing systems. These products...