

K160895 Initia Total Hip System & BIOCERAM AZUL(R) HEADNov 1, 2016
215 days to decisionK160895 · Product code: **LZO** · Orthopedic
Source: <https://www.510kdatabase.net/k160895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained, Metal/ceramic/polymer, Cemented Or Non-porous, Uncemented (LZO)
Date received	Mar 31, 2016
Decision date	Nov 1, 2016
Days to decision	215 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kyocera Medical Corporation
Location	Yodogawa-Ku, JP
Contact	Cheryl Hastings
510(k) history	1 submissions · 1 cleared · 2016-2016

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