

Product Type	Product	Specific device (if applicable)	N publications included	Manufacturer	CE mark date	Notes	FDA approval date	FDA pathway	Link to FDA report 1	Link to FDA report 2 /Comment	Predicates indicated to FDA
Hip Stem	Accolade II		12	Stryker	2012	From ODEP	2011	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103479.pdf		- Accolade TMZF hip stem - Restoration modular hip stem
Hip Stem	QUADRA H	Quadra H	7	Medacta	2003	From ODEP	2008	510(k) premarket notification	https://fda.report/PMN/K082792/8/K082792.pdf	https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072857.pdf	- Medacta Total Hip Prosthesis - Quadra S femoral stems, K072857, cleared on Feb. 4, 2008 - Predicate devices Quadra S: SL-PLUS® and SLR-PLUS® Stems, Plus K001942 Orthopedics AG SL-PLUS® Lateralized Stem, Plus orthopedics K021178 AG
Hip Stem	Filler 3ND		1	Biotechni	1997 / 2020	From ODEP	Not found				
Hip Stem	COLLO-MIS		2	LimaCorporate	2008	From ODEP	Not found				
Hip Stem	C-Stem AMT Total Hip System		2	DePuy Synthes	2005	From ODEP	2004	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf4/K042959.pdf		- C-stem (149829 18) cleared October 12, 1998 - Titan hip (K0001991) cleared August 31, 2000
Hip Stem	BiContact Cementless		8	Braun	1988	From ODEP	Not found				

Hip Stem	Avenir	Avenir Muller	4	Zimmer Biomet	2005	From ODEP	2013	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf12/K123392.pdf		- Corail AMTTM Hip Prosthesis, manufactured by DePuy Orthopaedics Inc, K042992, cleared February 11, 2005 - Zimmer® J'orolock MIS Stem, manufactured by Zimmer Inc, K071723, cleared March 03, 2008 - Predicate cemented stem: MS-30®) Hip Prosthesis, manufactured by Zimmer GmbH, *K993043, cleared December 2, 1999
Hip Stem	Alloclassic Zweymuller SL		19	Zimmer Biomet	1986	From ODEP	2003	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf3/K030373.pdf		ZweymuellerTMSL Femoral Stem (ref. K96210)
Hip Stem	MiniHip		8		2008	From ODEP	2010	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf8/K083312.pdf		a. Howmedica Osteonics Secur-Fit Max Hip and Secure-Fit Plus Max Hip Stems (K05 1738) b. Aesculap Implant Systems NMetha Short Stem Hip System (K080584) c. Zimmer MAYO Conservative Hip Prosthesis (K030733) d. Smith & Nephew MIS Hip Stem (K0724 17)
Hip stem	Stelia stem		0	Stemcup medical product	2020	From website https://stemcup.ch/wAssets/docs/zertifikate/305160_en_30816_eg_IIo_apx_20.pdf					

Hip Cup	Versafit CC Trio		8	Medacta	2004	From ODEP	2011	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103352.pdf		• K993082 Exactech AcuMatch™ Integrated HipSystem A-Series Porous Coated Acetabular Component • K050262 U2 Acetabular Component • K083 116 Versafitcup@ Double Mobility Acetabular Family, Medacta • K092265 Versafitcupt Double Mobility HighCross® UHMWPE Liners, Medacta International • K09 1069 Medacta Bone Screws, Medacta International • K003758 Allofit Acetabular Cup, Zimmer
Hip Cup	RM pressfit Vitamys		8	Mathys	2009	From ODEP	Not found				
Hip Cup	POLARCUP™ Cemented		3	Smith & Nephew	2000	From ODEP	2007	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf7/K070278.pdf		Biomet® Tni-Polar Systems, K991990
Hip Cup	Plasmacup SC		9	Braun	1997	From ODEP	Not found				
Hip Cup	IP X-LINKed acetabular cup		0	Waldemar Link	2010	From ODEP	Not found				
Hip Cup	Exceed ABT Cup		4	Zimmer Biomet	2006	From ODEP	Not found				

Hip Cup	EcoFit Cementless	EcoFit cementless cpTi coated	0	Implantcast	2007	From ODEP	2017	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163577.pdf		Biomet Taperloc® Complete (K101086, K103755) · Zimmer® M/L Taper Hip Prosthesis (K032726) · Biomet Taperloc® Complete Size 4mm and XR 123° (K120030) · Biomet Taperloc® Complete Microplasty System (K110400) · Zimmer Continuum™ and Trilogy® Integrated Taper (IT) Acetabular Systems (K091508) · Aesculap Excia Total Hip System - Plasmacup SC (K042344) and Plasmacup NSC (K061699) · Theken Companies iNSitu Total Hip System (K161184) · Smith & Nephew REFLECTION ACETABULAR COMPONENT (K932755, K022556) · Zimmer BIOLOX® Delta Ceramic Femoral Head (K071535, K130899) · Zimmer VerSys® Fiber Hip Prosthesis (K061786, K964769) · Total Joint Orthopedics Klassic HD Hip System (K143407)
Hip Cup	Cenator		0	Corin	1992	From ODEP	1993	510(k) premarket notification	https://fda.report/PMN/K925866		
Hip Cup	aneXys		0	Mathys	2015	From ODEP	Not found				

Hip Cup	ANA.NOVA cup		2	Implantec	2004	from Kaipel M, Prenner A, Bachl S, et al. Migration characteristics and early clinical results of a novel-finned press-fit acetabular cup. WIENER KLINISCHE WOCHENSCHRIFT 2014;126(7-8):208-11. doi: 10.1007/s00508-013-0488-y	Not found				
knee	ACS Unc, Unicondylar		0	implantcast GmbH	No date found		2020	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203341.pdf		Biomet Repicci II® Unicondylar Knee (K063515) Bodycad Unicompartmental Knee System (K163700, K181302) Medacta GMK® UNI (K161741) Zimmer Unicompartmental Knee System (K033363)
knee	balansys CR		4	Mathys	1998	First date of use: https://www.odep.org.uk/product/balansys-cr-cem-fixed-std-pe-domed-pat/	Not found				

knee	Innex Gender		0	Zimmer Biomet	2006	https://www.annualreports.com/HostedData/AnnualReportArchive/z/NYSE_ZBH_2006.pdf	Not found				
knee	LCS Complete		10	DePuy Synthes	2006	https://www.healio.com/news/orthopedics/2012/03/31/evolution-of-the-low-contact-stress-lcs-complete-knee-system-in-LCS-complete-document-have-more-justification	2011	Pre-market approval (P830055)	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P830055S115	Original LCS knee from 1985 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P830055	
knee	Logic PS		4	Exactech	2009	https://www.exac.com/wp-content/uploads/2020/07/712-25-40_RevA_Logic_Design_Rationale.pdf	2011	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf11/K110547.pdf		K093360 Optetrak Logic Total Knee System Exactech, Inc

knee	NexGen CR		18	Zimmer Biomet	1995	https://investor.zimmerbiomet.com/news-and-events/news/2015/27-03-2015-191939725	1995	510(k) premarket notification	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K946150		Not available in document
knee	Optetrak CR		0	Exactech	1994	https://www.exact.com/wp-content/uploads/2020/07/712-25-40_RevA_Logical_Design_Rationale.pdf	1995	510(k) premarket notification	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K932690		Not available in document
knee	Sigma High Performance Partial Knee		3	DePuy Synthes	2010	https://pubmed.ncbi.nlm.nih.gov/29147743/	2020	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193549.pdf		K070849 DEPUY GCK (SIGMA HP Partial) FEMORAL AND TIBIAL COMPONENTS K070267 DEPUY GCK (SIGMA HP Partial) TIBIAL COMPONENTS K061648 DEPUY GRADUATED COMPARTMENTAL KNEE (GCK) (SIGMA HP Partial) K101433 DEPUY ATTUNE KNEE SYSTEM
knee	TREKKING CR		2	SAMO	No date found		Not found				

knee	Vanguard CR		13	Zimmer Biomet	2003	https://www.prnewswire.com/news-releases/zimmer-biomet-launches-vanguard-individualized-design-knee-replacement-300330835.html	2004	510(k) premarket notification	https://www.accessdata.fda.gov/cdrh_docs/pdf3/K033489.pdf	Maxim® Accel Knee System also known as the Vanguard Knee System	AGO® Total Knee System Knee (K833921, K91 2245), Ascent™ Total Knee System (K982869, K994326), Maxim® Complete Knee System (K9151 32), Maxim® Accel Knee System (Vanguard) (K023546), Trabecular Metal Tibial and Patellar Components for the NexGen Knee System (K031462), Genesis 11 Total Knee System (K030612), Profix Total Knee System (K030623)
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