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- FOR IMMEDIATE RELEASE -

FDA Clears Chemically Crosslinked UHMWPE for Total Knees

Alchemist, LLC (ALC), a medical device technology company, today announced U.S. Food and Drug Administration (FDA) 510(k)¹ clearance of Total Joint Orthopedics, Inc.'s (TJO) Klassic® Knee System with ALC's AlchemXE® chemically crosslinked ultra-high molecular weight polyethylene (UHMWPE) technology. AlchemXE® blends dicumyl peroxide and vitamin E with UHMWPE during consolidation, then uses proprietary technology to crosslink the material, resulting in high wear resistance and excellent long-term oxidative stability without the need for radiation crosslinking. A proprietary heat treatment improves the mechanical properties and reduces the by-products of the peroxide chemistry. Implants machined from AlchemXE® are terminally gamma sterilized without any loss of oxidative stability. ALC partnered with Restoration Medical Polymers (RMP) for the development and large-scale production of this novel UHMWPE technology.

About Alchemist

Alchemist is a medical device technology development company focused on materials development to improve long-term performance of orthopaedic implants in total joint patients. To learn more about AlchemXE® please email info@thealchemist.com

About Total Joint Orthopedics

Total Joint Orthopedics, Inc. (TJO) is a Mission-Driven™ medical device company focused on improving the episode of care by pushing the boundaries in orthopedics. Using human-centered design, TJO has crafted its approach, Efficiency by Design®, as the cornerstone positioning them as pioneers in helping orthopedic stakeholders address the shifting healthcare landscape.

TJO's flagship Klassic® Knee and Klassic HD® Hip Systems feature modern implant innovations requiring a maximum of three instrument trays. These products improve operating room efficiency, relieve unnecessary burden on surgical staff, and reduce the overall cost of healthcare. Since TJO's founding in 2009, it has donated one joint for every ten implanted to Operation Walk. To learn more, please visit tjoinc.com.

About Restoration Medical Polymers

Restoration Medical Polymers (RMP) serves the orthopedic industry through the consolidation, development, and testing of implantable polymers; specifically Ultra-High Molecular Weight Polyethylene (UHMWPE). RMP provides UHMWPE bar stock via compression molding and ram extrusion, and near-net or net-shape molded parts via direct compression molding (DCM). RMP also provides polymer R&D and validation support, and mechanical/analytical testing services. RMP is ISO 13485:2016 certified and maintains ISO/IEC 17025:2017 accreditation for several test methods. Visit www.rmpoly.com to learn more.

¹ [K211877](https://www.fda.gov/oc/2022/01/17-fda-clears-chemically-crosslinked-uhmwpe-for-total-knees)

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