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BSI statement following the recent experience with the Clinical Evaluation Consultation Procedure (CECP) decision regarding the Zimmer Biomet Identity Shoulder System - (EMA/EX/0000228672)

BSI has reviewed the Clinical Evaluation Consultation Procedure (CECP) opinion (EMA/EX/0000228672) issued by the European Union (EU) Expert Panels Under Article 54 of the EU MDR/2017/745. This decision relates to the Zimmer Biomet Identity Shoulder System.

Upon review of the CECP decision, the primary focus of concern is the anatomical construct, specifically the taper adaptor connection, and its perceived novelty.

BSI Clarification

Based on the manufacturer's evidence evaluated during the conformity assessment, BSI concludes that the anatomical construct demonstrates low novelty. Comparable devices using modular constructs to address clinical needs are already available on the market, and no safety concerns have been identified that would challenge this assessment of novelty.

BSI continues to value the CECP process, and the expert opinion provided. However BSI acknowledges the limitations of this legal process and the issues associated with the limited access of information available to the EU expert panels, which may have led to this opinion.

The Notified Body is only permitted to submit the manufacturer's Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), The Post Market Clinical Follow Up (PMCF)Plan/Report and the Notified Body's Clinical Evaluation Assessment Report (CEAR) under Article 54. The legal process does not allow the expert panels to receive all technical documentation submitted by the manufacturer in support of the applicable General Safety and Performance Requirements (GSPRs) and MDR Article 61. This includes various technical test reports and other clinical assessment documentation that were used to support this claim of equivalence.

Based on the scientific data and justifications submitted by the manufacturer during the conformity assessment, BSI continues to accept the manufacturer's equivalence claim. The clinical data available for the equivalent device are considered sufficient to demonstrate the clinical safety and performance of the device under evaluation (DUE), in accordance with MDR Annex XIV Part A.

Upon receiving this CECP opinion, BSI carefully considered the reservations raised by the panel and communicated these with the manufacturer. The manufacturer was able to further satisfy BSI by providing some early subject-specific clinical data from outside of the EU that was not available to the manufacturer at time of submission for CECP. This additional clinical data was able to further demonstrate in support of the applicable General Safety and Performance Requirements (GSPRs).

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