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Abstract: The evaluation for European Union market approval of coronary stents falls under the Medical Device Directive that was adopted in 1993. Specific requirements for the assessment of coronary stents are laid out in supplementary advisory documents. In response to a call by the European Commission to make recommendations for a revision of the advisory document on the evaluation of coronary stents (Appendix 1 of MEDDEV 2.7.1), the European Society of Cardiology (ESC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI) established a Task Force to develop an expert advisory report. As basis for its report, the ESC-EAPCI Task Force reviewed existing processes, established a comprehensive list of all coronary drug-eluting stents that have received a CE mark to date, and undertook a systematic review of the literature of all published randomized clinical trials evaluating clinical and angiographic outcomes of coronary artery stents between 2002 and 2013. Based on these data, the TF provided recommendations to inform a new regulatory process for coronary stents. The main recommendations of the
task force include implementation of a standardized non-clinical assessment of stents and a novel clinical evaluation pathway for market approval. The two-stage clinical evaluation plan includes recommendation for an initial pre-market trial with objective performance criteria (OPC) benchmarking using invasive imaging follow-up leading to conditional CE-mark approval and a subsequent mandatory, large-scale randomized trial with clinical endpoint evaluation leading to unconditional CE-mark. The data analysis from the systematic review of the Task Force may provide a basis for determination of OPC for use in future studies. This paper represents an executive summary of the Task Force's report.