

DEVICE RAC EXAM STUDY GUIDE

Questions with 100% Correct Answers | Latest Version 2024 | Verified

510(k) Premarket Notifications for all of the following medical devices would be reviewed by CDRH's Office of Device Evaluation except:

- A) High Flux Hemodialyzer
- B) Blood specimen collection device
- C) Piston syringe
- D) Cardiopulmonary bypass blood tubing - ✓✓B

A 510(k) submission for any Class III device MUST include:

- A. Clinical results summary
- B. Hazards analysis evaluation
- C. Stability evaluation
- D. Certification and summary - ✓✓D

A clinical study sponsor's representative conducts periodic monitoring site visits for all of the following purposes EXCEPT to:

- A. Review raw data
- B. Ensure compliance with the protocol
- C. Review the protocol with the investigator
- D. Ensure the adequacy of the IRB and its procedures - ✓✓D

A company has been given a product from its British subsidiary to market for the first time in the US. The product is marketed in the EU. A project team gathered by the regulatory professional to review the information available for regulatory submission to FDA should:

- A. Focus on labeling and marketing since mutual recognition does not require complete technical review

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JE Gale



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