

Device RAC Exam Study Guide | Questions with 100% Correct Answers & Explanations | Verified | Latest Update 2024

Which division has primary jurisdiction over a vascular graft with an antibiotic based on primary mode of action?

- A. CDER
- B. CBER
- C. CDRH
- D. OCP - ✓✓C. CDRH

In this combination of a device and a drug, the primary mode of action is that of the vascular graft (device). The antibiotic is supportive in this case.

A company wants to modify its legally marketed device such that the modification does not affect the intended use or alter the fundamental scientific technology of the device. If the design outputs of the modified device meet the design input requirements, this change would be best filed as a(n):

- A. Special 510(k)
- B. Abbreviated 510(k)
- C. Traditional 510(k)
- D. De novo 510(k) - ✓✓A. Special 510(k)

A Special 510(k) is allowed if a modification to the legally marketed device is being made that relies on compliance with design controls, including design validation. The incentive provided for manufacturers to choose this option is that ODE intends to process special 510(k)s within 30 days of receipt. See the CDRH guidance published in 1998 entitled The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.

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Ying Liu



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