

# BTC Practice Test Questions and Answers

## 1. What is a 510(k) submission?

- A) A Medicare billing code
- B) A premarket notification demonstrating a new device is substantially equivalent to a legally marketed predicate device
- C) An annual FDA fee payment form
- D) A post-market surveillance report

## 2. What does 'off-label use' of a medical device mean?

- A) Using a device without reading the manual
- B) Using an FDA-cleared device for a purpose not included in its cleared indications
- C) Using a counterfeit device
- D) Using a device past its expiration date

## 3. What does 'as-found' data mean in a calibration record?

- A) Data recorded after adjustments are made
- B) The measurement values recorded before any adjustments during a calibration
- C) The equipment's factory default settings
- D) Data from the last preventive maintenance visit

## 4. What does the PDCA cycle stand for in quality management?

- A) Price, Demand, Cost, Assessment
- B) Plan, Do, Check, Act
- C) Prepare, Document, Certify, Approve
- D) Predict, Design, Create, Adapt

**Answers: 1-B 2-B 3-B 4-B**

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