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February 2018 Regulatory Quiz
Cleared or Not Cleared by FDA?
NBC Approval #35941
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1. FDA must ensure the safety of our nation's food supply, cosmetics, and products that emit radiation.
    a. True
    b. False

2. U.S. Dental Lab owners do not have a responsibility of ensuring that the patient contact materials used in their manufacture of dental devices are cleared by the FDA.
    a. True
    b. False

3. Patient contact materials include acrylic, porcelain, and zirconia but it does not include pressable ingots and implant components.
    a. True
    b. False

4. Some of the medical devices that fall under FDA's regulatory jurisdiction range from simple items like tongue depressors to complex technologies such as heart pacemakers.
    a. True
    b. False

5. FDA classifies medical devices into three classes. Class I devices are the most regulated while Class III are the least regulated.
    a. True
    b. False

6. Most Class I devices are exempt from Premarket Notification 510(k).
    a. True
    b. False

7. Most Class III devices require Premarket Approval.
    a. True
    b. False

8. Prior to commercial distribution of a device, it must be determined if the device requires a Premarket Notification 510(k).
    a. True
    b. False

9. There are no fees involved for medical device Premarket Notification 510(k).
    a. True
    b. False

10. Most dental devices are Class I or Class II.
    a. True
    b. False

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