Journal of Dental Technology
April 2026 Regulatory Quiz
Crucial Awareness: FDA, Orthodontic Appliances and the Labs that Make Them
NBC Approval # 57300

1. Dental laboratories that manufacture only patient-specific or patient-matched devices traditionally have not been a primary focus of FDA inspection.
    a. True
    b. False

2. Dental laboratories must always register with FDA even when they do not manufacture classified medical devices.
    a. True
    b. False

3. The exemption allowing some dental laboratories to avoid FDA registration is described in Title 21 of the Code of Federal Regulations, Part 807.
    a. True
    b. False

4. Dental laboratories may manufacture devices without registering if they use materials that have already been registered and listed by the material manufacturer.
    a. True
    b. False

5. Product code exist for domestically manufactured prosthetic devices such as crowns and dentures.
    a. True
    b. False

6. Orthodontic appliances are intended to move, align, or straighten existing teeth and jaw structures.
    a. True
    b. False

7. Some FDA inspectors have recently suggested that most orthodontic laboratories should register and list the appliances they manufacture.
    a. True
    b. False

8. Accessories used in orthodontic treatment, such as bands and brackets, are classified as Class II medical devices requiring a 510(k) submission.
    a. True
    b. False

9. The annual FDA registration and listing fee had increased to $11,423 as of 2026.
    a. True
    b. False

10. Rapid Palatal Expanders (RPEs) have drawn FDA attention partly because they may be used to treat conditions such as sleep apnea.
    a. True
    b. False

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