

1. Dental scan bodies are classified under the FDA's category "Endosseous dental implant accessories."
 - a. True
 - b. False
2. Scan bodies are classified as a Class II medical device by the FDA.
 - a. True
 - b. False
3. The Class I designation for scan bodies means there are no regulatory requirements.
 - a. True
 - b. False
4. Scan bodies are exempt from the need to submit 510(k) premarket notification to the FDA.
 - a. True
 - b. False
5. The 510(k) exemption makes the regulatory process more efficient for manufacturers.
 - a. True
 - b. False
6. Manufacturers of scan bodies are not required to register with the FDA.
 - a. True
 - b. False
7. FDA registration and listing must be renewed and updated whenever significant changes occur in manufacturing or product specifications.
 - a. True
 - b. False
8. Even though scan bodies are Class I exempt devices, they must still comply with FDA Quality System Regulation (QSR) requirements.
 - a. True
 - b. False
9. The 510(k) exemption exists because scan bodies are highly patient-specific devices.
 - a. True
 - b. False
10. General regulatory controls and fundamental quality system requirements apply to all dental laboratories.
 - a. True
 - b. False

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