number for the importer of the device, the 4-digit calendar year, and

a consecutive 5-digit number for each report filed during the year by the importer (e.g., 1234567-2016-00001, 1234567-2016-00002). If an importer does not have an assigned identification number, it should use all zeros in the appropriate space on the initial report, and continue to use zeros on subsequent reports until the FDA-assigned number is received. The importer would still enter the

4-digit calendar year and 5-digit sequence number.

- The **Exemption/Variance Number** identifies reports being submitted under the conditions of an FDA approved exemption or variance per 21 CFR Part 803.19. If the report being submitted is not the subject of an approved exemption or variance, the field should not be completed unless instructed by the FDA to use this field for a specific purpose.
- **Note**: In cases where a reporting site is registered as both a manufacturer and an importer, and the registration and/or FDA-assigned identification numbers are identical for both, then the 5-digit sequence number for reports submitted during the year by either one may NOT be duplicated. For example, for devices manufactured by the firm, the report number would consist of the registration number, calendar year, and a consecutive 5-digit number (e.g., 1234567-2016-00001, 1234567-2016-00002, and so on). For devices imported by the firm, the registration number and year would remain the same, but the 5-digit sequence number must be different (e.g., 1234567-2016- 00003, 1234567-2016-00004, and so on).

(continued on next page)

Indicate the ethnicity of the patient. Choose only one response. Please do NOT make a best guess.

A6: Race

Indicate the race of the patient as reported by the patient. You may choose multiple answers for race. Please do NOT make a best guess.

(continued on next page)