the frequency and severity of alopecia during chemotherapy in which alopecia-inducing chemotherapeutic agents are used.

(b) Classification—Class II (special controls). The special controls for this device are:

1. Non-clinical performance testing must demonstrate that the device meets all design specifications and performance requirements, and that the device performs as intended under anticipated conditions of use. This information must include testing to demonstrate accuracy of the temperature control mechanism.

2. Performance testing must demonstrate the electromagnetic compatibility and electrical safety of the device.

3. Software verification, validation, and hazard analysis must be performed.

4. The patient contacting components of the device must be demonstrated to be biocompatible. Material names must be provided.

5. Labeling must include the following:

   i. A statement describing the potential risk of developing scalp metastasis.

   ii. Information on the patient population and chemotherapeutic agents/regimen for which the device has been demonstrated to be effective.

   iii. A summary of the non-clinical and/or clinical testing pertinent to use of the device.

   iv. A summary of the device technical parameters, including temperature cooling range and duration of cooling.

   v. A summary of the device- and procedure-related adverse events pertinent to use of the device.

   vi. Information on how the device operates and the typical course of treatment.

   vii. Patient labeling must be provided and must include:

      i. Relevant contraindications, warnings, precautions, and adverse effects/complications.

      ii. Information on how the device operates and the typical course of treatment.

      iii. Information on the patient population for which there is clinical evidence of effectiveness.

      iv. The potential risks and benefits associated with use of the device.

      v. Postoperative care instructions.

   vi. A statement describing the potential risk of developing scalp metastasis.

DEPARTMENT OF STATE

22 CFR Part 41
[Public Notice: 9439]
RIN 1400–AD17
Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act, as Amended

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This final rule amends the Visa Waivers of Ineligibility Act of 1990 to ensure that nonimmigrants who qualify for waiver of ineligibility under Section 212(d)(3) of the Act are properly documented under the immigration and nationality laws.

DATES: This rule is effective March 1, 2016.

FOR FURTHER INFORMATION CONTACT: Presented at the Department of State.

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