March 4, 2024

Maryann Ayoade (LV Liberty Vision Corporation Model 1 Ytrrium-90 Disc and iWand® contact)
Daniel Shaw (Akesis Galaxy RTi contact)
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Dear Ms. Ayoade and Mr. Shaw,

The OAS Executive Board (Board) appreciates the opportunity to comment on RCPD-23-006, the Opportunity to Provide Comments on Draft Licensing Guidance for the Akesis Galaxy RTi and the LV Liberty Vision Corporation Model 1 Yttrium-90 Disc and iWand® Ophthalmic System. After reviewing the draft guidance, and after receiving comments from our Agreement State partners, the Board has the following comments on the draft guidance:

Akesis Galaxy RTi draft licensing guidance:

1. On Page 3, Section 4.1.1 describes the different pathways a physician can be named as an Authorized User (AU) for this type of use. Pathway 1) appears to exclude AUs that are listed on a license for other types of gamma stereotactic radiosurgery (GSR) authorized by 10 CFR 35.1000. This section should be revised to include AUs that are authorized for other 35.1000 GSR units as the Akesis Galaxy RTi seems to be more similar to currently authorized 35.1000 GSR units than 35.600 GSR units.

2. On Page 7, the section describing Section 35.610 contains an open parenthesis for the information required to be retained.

3. Within the Liberty Vision guidance, there is the following statement in Section 3 (Licensing Guidance): If an applicant commits to the guidance provided below, the applicant must follow commitments described with the use of the word "should." This statement is also found in the licensing guidance for other 35.1000 GSR units but is not included in the Licensing Guidance section of the Akesis Galaxy RTi guidance. This statement should be included.

4. Within the 35.1000 Determination Checklist, the following items were noted:

    a. For Section 35.635, the Deviation Explanation and Specifics for Licensing Guidance section (top of page 6), the last comment should include the word 'not' instead of the word 'no'.
    b. For Section 35.2080, both Yes and N/A are checked.
    c. For Section 35.2075, Yes is checked but N/A seems more appropriate.
    d. For Section 35.2632, N/A is checked but Yes seems more appropriate.

LV Liberty Vision Corporation Model 1 Ytrrium-90 Disc and iWand® Ophthalmic System guidance:

1. Section 5.2.3 includes the training and experience pathway for an Ophthalmic Physicist. However, in Section 5.2, there is no mention if an Ophthalmic Physicist is required for this type of medical use, and there are no other sections identifying when an Ophthalmic Physicist is required or if that individual is in lieu of a Medical Physicist. The role of the Ophthalmic Physicist should be clarified within the guidance.

2. Within Section 5.2.2, the following items were noted:

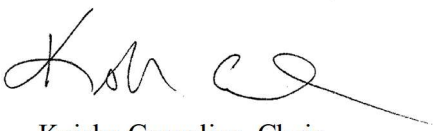
    a. Section A.1, the 1 is crossed out at the beginning of the section.
    b. In Sections A.1 and B.1, the capitalized 'AND' is used for identifying the device and clinical use T&E criteria. However, in A.2 and B.2, the lower case 'and' is used for identifying the device and clinical use T&E criteria with the additional written attestation requirement. The capitalized 'AND' or lower case 'and' should be used consistently.

3. Within the 35.1000 Determination Checklist, the following items were noted:

    a. For Section 35.75, does the medical use meet the rule since the materials are not implanted, or should this section be N/A?
    b. For Section 35.2060, both No and N/A are checked.
    c. For Section 35.2075, does the medical use meet the rule since the materials are not implanted, or should this section be N/A?
    d. On Page 14, Directions of Use section, the fourth bullet point includes two sub-bullets that include references to HDR requirements. Are these needed for this medical use? Also, with respect to the iWand®, is that item considered the unit or the console?

Once again, the Board appreciates this opportunity to comment. We are available should you have any questions or need clarifications to our responses.

Sincerely,



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