October 28, 2024

Mark Falkowski
Pyrexar Medical Inc.
1825 West Research Way, Ste E
Salt Lake City, Utah, 84119

Sent via email to: Mark.Falkowski@pyrexar.com

Re: FDA-2024-P-2846 – Petition for Reclassification

Dear Petitioner:

This is a response to the petition you submitted on behalf of Pyrexar Medical Inc. regarding the BSD-2000 Hyperthermia System, received by FDA on June 13, 2024. In your petition you request that FDA reclassify the BSD-2000 Hyperthermia System from a Class III to a Class II medical device under section 513(e) of the Federal Food, Drug, and Cosmetic Act.

As an initial matter, devices that were not in commercial distribution prior to May 28, 1976, (generally referred to as "postamendments devices") are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Postamendments devices can be reclassified in accordance with section 513(f)(3) of the FD&C Act. The BSD-2000 Hyperthermia System is a postamendments device automatically classified into class III and currently marketed under a humanitarian device exemption (HDE) in accordance with section 520(m) of the FD&C Act.[1] As such, section 513(f)(3) of the FD&C Act is the appropriate pathway for reclassification of devices such as the BSD-2000 Hyperthermia System. Under section 513(f)(3) of the FD&C Act, FDA may initiate the reclassification of a class III device, or the manufacturer or importer of the device may petition for the issuance of an order classifying the device into class II or class I. Notwithstanding that your petition was filed in error under section 513(e) of the FD&C Act, FDA denies your petition under 21 CFR 860.130(e) for the reasons discussed herein.

Your petition proposes reclassifying the BSD-2000 Hyperthermia System from a Class III to a Class II medical device based on "demonstrated significant clinical benefits and safety profiles aligning with the Class II classification criteria." In order to reclassify a class III device to class II, FDA needs to determine that there is sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness for the device.[2] Your petition does not provide the information necessary for FDA to make such determination.

[1] FDA Humanitarian Device Exemption (HDE) Database, BSD-2000 Hyperthermia System, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H090002.
[2] Section 513(a)(1)(B) of the FD&C Act.

Although your petition provides a list of reasons to support reclassification to class II, such as "clinical efficacy and safety," "proven track record," "technological advancements," and "alignment with regulatory precedents,"[3] your petition does not provide adequate detail regarding these and other enumerated reasons upon which FDA could conduct an assessment and make a determination regarding reclassification. For example, your petition states that "[n]umerous clinical studies and trials have evidenced its efficacy" and "[t]he system's safety profile is well-documented, with minimal adverse effects reported when used according to the prescribed protocols."[4] However, you do not provide any additional information or materials to support these statements other than a link to the "Pyrexar Medical Clinical results on our web page," which only provides a general list of clinical studies that used the BSD-2000 Hyperthermia System.[5] Please note that petitions for reclassification must include as appendices copies of source documents from which new information used to support the petition has been obtained.[6] In addition, we note that the studies linked on this web page include studies for several different types of cancers. However, the BSD-2000 Hyperthermia System, marketed under an HDE, is only indicated "for use in conjunction with radiation therapy for the treatment of cervical carcinoma patients who normally would be treated with combined chemotherapy and radiation but are ineligible for chemotherapy due to patient related factors."[7] Therefore, the intended use for which you are requesting reclassification is not clear, and it is not clear which studies referenced on this web page provide the relevant evidence or data to support your statements regarding clinical safety and effectiveness.

Furthermore, your petition states "[o]ncologists and medical professionals worldwide have validated its performance, reliability, and positive impact on patient care. The accumulated data from these practical applications support the system's capability to deliver consistent therapeutic benefits without introducing significant risks."[8] However, your petition does not provide any data on the device performance, reliability, or patient impact, nor any additional information to support these conclusions regarding the risk-benefit analysis.

Similarly, your petition does not provide the necessary information to support your statements regarding "technological advancements," "streamlined access and reduced costs," and "alignment with regulatory precedents."[9]

As such, FDA denies this petition. We note that should you wish to request reclassification for other devices in the future, you should first determine whether the device falls within section 513(e) or (f) of the FD&C Act and then refer to 21 CFR 860.123 for details on the content and

[3] Petition, pp. 1-2.
[4] Petition, p. 1.
[5] Petition, p. 2.
[6] 21 CFR 860.123(a)(7).
[7] FDA Humanitarian Device Exemption (HDE) Database, BSD-2000 Hyperthermia System Approval Letter, available at https://www.accessdata.fda.gov/cdrh_docs/pdf9/H090002A.pdf.
[8] Petition, p. 1.
[9] Petition, pp. 1-2.

form for a Petition for Reclassification.

If you have any questions about this response, please contact Rachel Park of our Office of Policy at rachel.park@fda.hhs.gov or 301-796-7944.

Sincerely,

Ellen J. Flannery -S Digitally signed by Ellen J. Flannery -S
Date: 2024.10.28 12:06:04 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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