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June 6th, 2024
Pyrexar Medical Inc.
1825 West Research Way, Ste E
Salt Lake City, Utah 84119

Dear Regulatory Authority/Review Board,

I am writing to submit a petition for the reclassification of the BSD-2000 from Class III to Class II under Section 513(e) of the Federal Food, Drug, and Cosmetic Act. This petition is being submitted on behalf of Pyrexar Medical Inc., the manufacturer of BSD-2000.

I wanted to reach out to you as the CEO of Pyrexar Medical Inc. to advocate for reclassifying our BSD-2000 Hyperthermia System from a Class III to a Class II medical device. The BSD-2000 system, designed to deliver targeted hyperthermia therapy, has demonstrated significant clinical benefits and safety profiles aligning with the Class II classification criteria.

Clinical Efficacy and Safety
Over the years, hyperthermia has gained recognition as an effective adjuvant treatment in oncology. The BSD-2000 system specifically targets tumor sites, raising the temperature to enhance the effectiveness of radiotherapy and chemotherapy. Numerous clinical studies and trials have evidenced its efficacy in improving patient outcomes, including higher response rates and extended survival times. The system's safety profile is well-documented, with minimal adverse effects reported when used according to the prescribed protocols.

Proven Track Record
The BSD-2000 system has been used for several years across multiple healthcare facilities globally. Oncologists 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, thus justifying a reclassification to Class II.

Technological Advancements
The BSD-2000 system incorporates advanced technology that ensures precise control and delivery of hyperthermia therapy. Its design includes robust safety mechanisms and failsafe features that minimize the risk of device-related complications. This technological sophistication allows for more accessible and effective therapy management, aligning with the regulatory expectations for Class II devices.

Streamlined Access and Reduced Costs
Reclassifying the BSD-2000 system as a Class II device will streamline the regulatory process, facilitating easier access for healthcare providers and patients. This change will reduce the associated administrative and financial burdens, thereby promoting wider adoption of hyperthermia therapy. Ultimately, this will lead to improved patient care and potentially lower healthcare costs due to the enhanced effectiveness of combined treatment modalities.

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Alignment with Regulatory Precedents

Several medical devices with comparable risk profiles and clinical applications have successfully transitioned to Class II classifications. The BSD-2000 system's established safety and efficacy align with these precedents, underscoring the appropriateness of reclassification.

Conclusion

In light of the compelling clinical evidence, proven safety record, technological advancements, and potential for broader healthcare benefits, we strongly urge the regulatory authority to consider the reclassification of the BSD-2000 Hyperthermia System from Class III to Class II. This reclassification will reflect the device's risk profile and ensure more patients benefit from this innovative, life-enhancing treatment. We have over one hundred and sixty-five systems installed worldwide and continue to install them monthly. We need your help to provide the BSD-2000 to the United States Medical market to enhance the killing of cancer with radiation and chemotherapy.

Based on the provided evidence and data, we believe that the BSD-2000 meets the criteria for reclassification from Class III to Class II. We respectfully request the FDA to consider this petition and reclassify the device accordingly.

We appreciate your consideration of this petition and are available to provide any additional information or clarification that may be required.

We appreciate your attention and can provide any additional information or clarification data on safety.

I've provided Pyrexar Medical Clinical results on our web page and here is the URL for your review.

https://www.pyrexar.com/clinical/bsd-2000-clinical-studies

Sincerely,

Mark Falkowski

CEO, Pyrexar Medical Inc.