June 21, 2020

Thomas J. Quinn

Re: Citizen Petition – Docket Number FDA-2013-P-0997

Dear Mr. Quinn:

This is a response to your citizen petition received on August 13, 2013, requesting that the Food and Drug Administration (FDA) amend 21 CFR Part 1030, Performance Standards for Microwave and Radio Frequency Emitting Products, to include Nuclear Magnetic Resonance Imaging (product code LNH and LNI). Specifically, your petition requests that FDA "amend 21 CFR [Part]1030 to include 1030.30, performance standards for Nuclear Magnetic Resonance Imaging" and provides specific language for the performance standards for these products.

FDA appreciates your concerns regarding the safety of these products. However, in accordance with 21 CFR 10.30(e) and for the reasons described below, FDA denies your petition.

ANALYSIS

Although your petition provides proposed performance standards for Nuclear Magnetic Resonance Imaging Systems, your petition fails to provide an explanation as to why such performance standards are necessary for the protection of public health and safety. In your petition you simply state that:

> "The health effects of microwave energy on the human body are well known and documented. The regulatory control of microwave energy for Nuclear Magnetic Resonance Imagining systems is the responsibility of the Food and Drug Administration, see 47 CFR part 18.
>
> To date there are no performance standards for Nuclear Magnetic Resonance Imaging systems in 21 CFR. 21 CFR has a section for microwave energy devices, section 1030 which currently regulates the performance standards for microwave ovens only."

There is no other information in your petition to justify that the existing regulatory controls are not sufficient for the protection of public health and safety. Nor does your petition provide any representative information that are known to you, which are unfavorable to your proposed amendments.

As such your petition provides no information to support that the performance standards you propose are necessary for the protection of public health and safety. FDA considers current

regulatory controls and activities to be appropriate to monitor and provide for reasonable assurance of the safety and effectiveness of Nuclear Magnetic Resonance Imaging products. FDA regulates these products as medical devices and their safety is evaluated prior to market entry through the 510(k) premarket notification process. These devices are also subject to other regulatory controls under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations, including but not limited to: good manufacturing practice requirements under section 520(f) of the FD&C Act and 21 CFR Part 820, adverse event reporting requirements under section 519 of the FD&C Act and 21 CFR Part 803, labeling requirements under 21 CFR Part 801, and prohibitions on adulteration and misbranding under sections 501 and 502 of the FD&C Act. FDA dedicates resources to actively monitor the safety and effectiveness of these devices. For example, manufacturers of these devices are evaluated in periodic inspections. FDA also recognizes consensus standards specific to Nuclear Magnetic Resonance Imaging products and participates in consensus standards development with stakeholders. In addition, Nuclear Magnetic Resonance Imaging products are also electronic products as defined in section 531(2) of the FD&C Act. As such, they are subject to the radiological health requirements in 21 CFR Chapter I, Subchapter J, as applicable, including but not limited to, reporting and recordkeeping requirements (21 CFR Part 1002) and notification and corrective actions for defective electronic products (21 CFR Parts 1003 and 1004).

In conclusion, for the reasons discussed above, your petition fails to demonstrate that the current regulatory controls for Nuclear Magnetic Resonance Imaging products are insufficient and that the performance standards proposed in your petition are necessary for the protection of public health and safety. Therefore, FDA is denying your petition. If you have any questions, please contact Myrna Hanna in our Office of Policy, Regulatory Documents and Special Projects Team, by e-mail at myrna.hanna@fda.hhs.gov or (301) 796-5739.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2020.06.21 18:55:46 -04'00'

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