October 28, 2024

Gloria Pesce Delfino, Head of Regulatory Affairs
and Technical Documentation
Metaltronica Spa
Via delle Monachelle, 66-00071
Pomezia (RM), Italy

Sent via email to: gloria.pescedelfino@metaltronica.com

Re: Citizen Petition – FDA-2024-P-2215

Dear Petitioner:

This is an interim response to the petition dated May 02, 2024, filed by the Food and Drug Administration (FDA) on May 05, 2024. In the petition, you requested FDA "reclassify tomo digital mammography devices (product code OTE) to the same risk class and premarket submission type as Full Field digital mammography FFDM (product code MUE) devices." More specifically, you requested that FDA "reclassify this product from class III to class II and change the required premarket submission type from a PMA to a 510(k)."

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations on citizen's petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Kimberly Viola of our Office of Policy at kimberly.viola@fda.hhs.gov or (240) 402-3549.

Sincerely,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2024.10.28 11:53:37 -04'00'

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