---------- Original Message ----------
From: "DICE" [dice@fda.hhs.gov]
Sent: 9/5/2023 12:39 PM
To: gm@marchandinstitute.org <gm@marchandinstitute.org>
Subject: Support at FDA/DICE Re:Power morcellators

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

The May 2023 guidance entitled “Non-Clinical Performance Assessment of Tissue Containment Systems Used During Power Morcellation Procedures” does not address the “black box” warning on laparoscopic power morcellators. The new guidance is limited to tissue containment systems, therefore the "black box" warning is still in place.

The December 2020 guidance entitled “Product Labeling for Laparoscopic Power Morcellators” includes the black box warning and has not been revised to date.

If you have any further questions, feel free to write us back at dice@fda.hhs.gov I hope this information is helpful.

Sincerely,
Consumer Team
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Original Message
From: gm@marchandinstitute.org
Sent: 9/2/2023

Subject: Power morcellators
Message:

Is there still a "black box" warning on power morcellators or does the new May 2023 "final guidance" now supersede this? Does this remove the black box?

Thank you!

Greg Marchand