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FDA bans ESDs for self injurious behaviour

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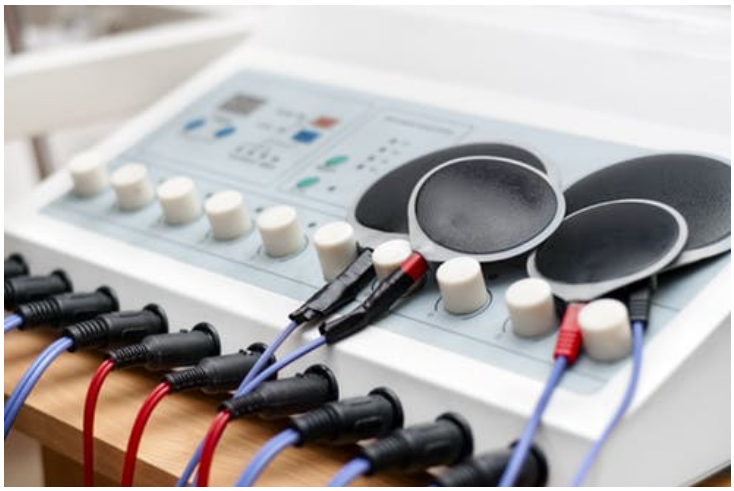
Devices Found to Present Unreasonable and Substantial Risk of Illness or Injury



After careful consideration, the U.S. Food and Drug Administration (FDA) has published a final rule to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior because they present an unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated through new or updated device labeling.

"Since ESDs were first marketed more than 20 years ago, we have gained a better understanding of the danger these devices present to public health," said William Maisel, M.D., M.P.H., director of the Office of Product Evaluation and Quality in the FDA's Center for Devices and Radiological Health. "Through advancements in medical science, there are now more treatment options available to reduce or stop self-injurious or aggressive behavior, thus avoiding the substantial risk ESDs present."

ESDs administer electrical shocks through electrodes attached to the skin of individuals to immediately interrupt self-injurious or aggressive behavior or attempt to condition the individuals to stop engaging in such behavior.

Evidence indicates a number of significant psychological and physical risks are associated with the use of these devices, including worsening of underlying symptoms, depression, anxiety, posttraumatic stress disorder, pain, burns and tissue damage. In addition, many people who are exposed to these devices have intellectual or developmental disabilities that make it difficult to communicate their pain. Evidence of the device's effectiveness is weak and evidence supporting the benefit-risk profiles of alternatives is strong.

As the risks presented by ESDs meet the agency's definition of unreasonable and substantial and cannot be corrected or eliminated through new or updated labeling, banning the product is necessary to protect public health.

The act of banning a device is rare and the circumstances under which the agency can take this action is stringent, but the FDA has the authority to take this action when necessary to protect the health of the public. The FDA has only banned two other medical devices since gaining the authority to do so.