

Stand on scales (that do not measure BMI) like our iScale® and iScale Plus, are considered **exempt** Class I medical devices, meaning that they meet the FDA's requirements of a medical device; however, they are not subject to the Premarket Notification Procedures, commonly referred to as the 510k FDA clearance process.

[According to Section 201\(h\)\(1\) of the Food, Drug, and Cosmetic Act](#), a device is:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- (A) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (C) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

According to the Center for Medicare and Medicaid Services' (CMS) [2021 physician fee schedule final ruling](#) regarding eligible devices for RPM (which has gone unchanged and is still in standing for the 2024 calendar year), "the device must be a medical device as defined by the FDA.' CPT simply specifies that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). As discussed in the CY 2021 PFS proposed rule (85 FR 50118), we found no language in the CPT Codebook indicating that a medical device must be FDA cleared as some stakeholders suggested, although such clearance may be appropriate."

All of our scales have been registered with the FDA. You can search the registry using the below UDI numbers.

iScale Plus: 00860010013717

iScale: 00860007782282

Please see the accompanying FDA Code of Federal Regulations for more information on the classification and exemption of stand on scales.

Sincerely,

Erez Pick
Vice President, Operations