rather than culture or immunoassay technology; or  
(c) The device is an in vitro device that is intended:  
(1) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;  
(2) For use in screening or diagnosis of familial or acquired genetic disorders, including inborn errors of metabolism;  
(3) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy;  
(4) For assessing the risk of cardiovascular diseases;  
(5) For use in diabetes management;  
(6) For identifying or inferring the identity of a microorganism directly from clinical material;  
(7) For detection of antibodies to microorganisms other than immunoglobulin G (IgG) or IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma;  
(8) For noninvasive testing as defined in §812.3(k) of this chapter; and  
(9) For near patient testing (point of care).  
[65 FR 2321, Jan. 14, 2000]  
§ 888.1240 AC-powered dynamometer.  
(a) Identification. An AC-powered dynamometer is an AC-powered device intended for medical purposes to assess neuromuscular function or degree of neuromuscular blockage by measuring, with a force transducer (a device that translates force into electrical impulses), the grip-strength of a patient’s hand.  
(b) Classification. Class II.  
§ 888.1250 Nonpowered dynamometer.  
(a) Identification. A nonpowered dynamometer is a mechanical device intended for medical purposes to measure the pinch and grip muscle strength of a patient’s hand.  
(b) Classification. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.  
§ 888.1500 Goniometer.  
(a) Identification. A goniometer is an AC-powered or battery powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.  
(b) Classification. (1) Class I (general controls) for a goniometer that does not use electrode lead wires and patient cables. This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to §888.9.  
(2) Class II (special controls) for a goniometer that uses electrode lead wires and patient cables. The special controls consist of:  
(i) The performance standard under part 898 of this chapter, and  