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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).

Subpart B—Diagnostic Devices

§ 888.1100 Arthroscope.
(a) Identification. An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscopy and accessories also is intended to perform surgery within a joint.
(b) Classification. (1) Class II (performance standards).

§ 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 888 of this chapter, and