§ 882.5975 Human dura mater.

(a) Identification. Human dura mater is human pachymeninx tissue intended to repair defects in human dura mater.

(b) Classification. Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Human Dura Mater.” See §882.1(e) for the availability of this guidance.

(c) Scope. The classification set forth in this section is only applicable to human dura mater recovered prior to May 25, 2005.