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- use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass-assisted devices);
- use as a critical component in medical devices that support or sustain human life; or
- use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.

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