must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of tissues that are necrotic, friable, or have altered integrity.

(B) Unless available information demonstrates that the specific warnings do not apply, the labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use including:

(*1*) Avoidance of use of the stapler to staple tissue outside of the labeled limits for maximum and minimum tissue thickness;

(*2*) Avoidance of obstructions to the creation of the staple line and the unintended stapling of other anatomic structures;

(*3*) Avoidance of clamping and unclamping of delicate tissue structures to prevent tissue damage;

(*4*) Avoidance of use of the stapler on the aorta;

(*5*) Establishing proximal control of blood vessels prior to stapling where practical and methods of blood vessel control in the event of stapler failure;

(*6*) Ensuring stapler compatibility with staples; and

(*7*) Risks specifically associated with the crossing of staple lines.

(C) Specific user instructions for proper device use including measures associated with the prevention of device malfunction, and evaluation of the appropriateness of the target tissue for stapling.

(D) List of staples with which the stapler has been demonstrated to be compatible.

(E) Identification of key performance parameters and technical characteristics of the stapler and the compatible staples needed for safe use of the device.

(F) Information regarding tissues on which the stapler is intended to be used.

(G) Identification of safety mechanisms of the stapler.

(H) Validated methods and instructions for reprocessing of any reusable device components.

(I) An expiration date/shelf life.

(x) Package labels must include critical information and technical characteristics necessary for proper device selection.

[86 FR 16204, Oct. 8, 2021]

§ 878.4750 Implantable staple.

(a) *Identification.* An implantable staple is a staple-like device intended to connect internal tissues to aid healing. It is not absorbable.

(b) *Classification.* Class II.

§ 878.4755 Absorbable lung biopsy plug.

(a) *Identification.* A preformed (polymerized) absorbable lung biopsy plug is intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies. Upon deployment into the biopsy tract, the plug expands to fill the biopsy void and remains in place until resorbed.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate deployment as indicated in the accompanying labeling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.

(3) In vivo evaluation must demonstrate performance characteristics of the device, including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.

(4) Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.

(5) Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.

(6) The device must be demonstrated to be biocompatible.

(7) Labeling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate