

FDA CDRH General and Plastic Surgery Devices Advisory Committee Meeting

May 30, 2019

Gaithersburg Holiday Inn,
Grand Ballroom,
2 Montgomery Village Ave.,
Gaithersburg, MD 20879

As required by section 513(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Food and Drug Administration (FDA) is convening the General and Plastic Surgery Devices Advisory Panel (the Panel) for the purposes of obtaining recommendations about the reclassification of surgical staplers.

FDA is holding this panel meeting to obtain input on the risks and benefits of surgical staplers for internal use. The Panel will be asked to recommend to FDA whether surgical staplers should be up classified from Class I (subject only to General Controls) into Class II (subject to General and Special Controls). The Panel will be asked to discuss the types of evidence (including clinical evidence) that would be helpful to support certain indications as well as appropriate controls necessary to mitigate the risks to health and assure the safety and effectiveness of these devices.

AGENDA – Surgical Staplers for Internal Use

9:00 a.m.	Call to Order, Opening Remarks and Introduction of the Committee	Panel Chair
9:05 a.m.	Conflict of Interest Statement	Designated Federal Officer
	Introduction	
9:15 a.m.	Introductory Remarks and Device Description	Dale Rimmer, Ph.D.
9:25 a.m.	Clarifying Questions from the Panel	
	External Speaker Presentations	
9:30 a.m.	Safety Issues Related to Surgical Staplers	ECRI-Scott Lucas, Ph.D., P.E.
9:50 a.m.	Clarifying Questions from the Panel	
9:55 a.m.	Industry Presentations	
10:55 a.m.	Clarifying Questions from the Panel	
	FDA Presentations	
11:00 a.m.	History and Clinical Safety Aspects of Surgical Stapler Special Controls	George Gibeily, M.D. FACS
11:20 a.m.	Clarifying Questions from the Panel	
11:25 a.m.	Surgical Stapler/Staple Medical Device Reporting (MDR)	Karen Nast, M.S., RN
11:35 a.m.	Clarifying Questions from the Panel	
11:40 a.m.	Current Testing Methods and Proposed Risks, Mitigations, and Special Controls	Dale Rimmer, Ph.D.
11:55 a.m.	Clarifying Questions from the Panel	
Noon	Lunch	

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AGENDA – Surgical Staplers for Internal Use

Open Public Hearing

1:00 p.m. Open Public Hearing

2:00 p.m. Clarifying Questions from the Panel

FDA Questions

2:05 p.m. Questions to the General and Plastic Surgery Devices Panel

4:00p.m. Day 1 - adjournment