Regulatory issues in the United States pertinent to abdominal wall reconstruction

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The invited review by Binita Asher, MD, Jiyoung Dang Ph.D., David Krause Ph.D. and Markham Luke, MD, PhD is the first of a two-part series from the Office of Device Evaluation at the FDA/CDRH/ODE/DSORD (Food and Drug Administration/Center for Devices and Radiological Health/Office of Device Evaluation/Division of Surgical, Orthopedic, and Restorative Devices). They discuss regulatory issues in the United States pertinent to abdominal wall reconstruction. The Editors felt that this was important since we receive so many submissions dealing with various devices for hernia repair. The second submission will deal with fixation appliances, biological glues, and surgical adhesives.

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