



总局办公厅关于实施《医疗器械召回管理办法》有关事项的通知

Notice of the CFDA General Office on Relevant Matters about the Implementation of the Administrative Measures for Medical Device Recall

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各省、自治区、直辖市食品药品监督管理局：

Food and Drug Administration of all the provinces, autonomous regions and direct-controlled municipalities,

《医疗器械召回管理办法》（国家食品药品监督管理总局令第29号，以下简称《办法》）自2017年5月1日起正式实施，为贯彻落实《办法》有关要求，保障人民群众用械安全，督促医疗器械生产企业落实产品质量安全主体责任，现将有关事项通知如下：

The *Administrative Measures for Medical Device Recall* (Decree No. 29 of China Food and Drug Administration, hereinafter referred to as the *Measures*) are put into implementation on May 1, 2017 officially. In order to implement relevant requirements in the *Measures*, safeguard the usage safety of medical device for the masses, supervise and urge the medical device manufacturers to implement the entity responsibility for the product quality safety, relevant matters are notified as follows:

一、医疗器械召回组织工作要求

I. Job Requirements for the Organization of Medical Device Recall

省级食品药品监督管理部门要高度重视医疗器械召回工作，以保障医疗器械产品安全为出发点，切实加强对本省医疗器械召回的组织工作。各级食品药品监管部门要加强对《办法》的宣贯培训，加强对医疗器械生产经营企业、使用单位的宣传教育，督促企业切实履行召回义务，确保《办法》落实落地。

The food and drug administration at the provincial level shall pay high attention to the medical device recall, regard safeguarding the product safety of medical device as a starting point and reinforce the organization of medical device recall inside this province effectively. Food and drug

regulatory departments at different levels shall strengthen the propagation, implementation and training on the *Measures*, reinforce the propagation and education among the medical device producers and dealers and users, urge the enterprises to perform the recall obligation effectively and assure the implementation of the *Measures* properly.

二、医疗器械召回报告要求

II. Reporting Requirements of the Medical Device Recall

医疗器械产品注册人或者备案人、进口医疗器械的境外制造厂商履行《办法》中生产企业的义务，承担相应法律责任。

Entity registering or filing the medical device product or overseas manufacturer of the imported medical device shall fulfill the obligations as a manufacturer in the *Measures* and shoulder the corresponding legal responsibilities.

医疗器械生产企业作出医疗器械主动召回决定的，应当按照《办法》第十六条规定，立即向所在地省级食品药品监督管理部门和批准该产品注册或者办理备案的食品药品监督管理部门提交医疗器械召回事件报告表（附件 1），并在 5 个工作日内将调查评估报告和召回计划提交至所在地省级食品药品监督管理部门和批准注册或者办理备案的食品药品监督管理部门备案。

Where the medical device manufacturer decides to recall the medical device voluntarily, such manufacturer shall submit the medical device recall incident report (Attachment 1) to the local provincial food and drug administration and food and drug administration approving such product registration or handling the filing without delay in accordance with Article 16 of the *Measures* and shall, within 5 business days, submit the investigation assessment report and recall plan to the local provincial food and drug administration and food and drug administration approving such product registration or handling the filing for placing the same on file.

（一）进口医疗器械和境内第三类医疗器械实施主动召回的，生产企业应当按上述要求将相关材料报至企业所在地省级食品药品监督管理部门和 国家食品药品监督管理总局（以下简称总局）。

(I) Where the imported medical device and Class III medical device within the Chinese territory are recalled voluntarily, the manufacturers shall submit the relevant materials to the provincial food and drug administration at the place where the manufacturer is located and the China Food and Drug Administration (hereinafter referred to as the CFDA) according to the aforesaid requirements.

（二）境内第二类医疗器械实施主动召回的，生产企业应当按上述要求将相关材料报至企业所在地省级食品药品监督管理部门。

(II) Where class II medical device within the Chinese territory is recalled voluntarily, the manufacturer shall submit the relevant materials to provincial food and drug administration at the place where the manufacturer is located according to the aforesaid requirements.

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