Circular of the National Medical Products Administration on the Issuance of the Guidance on the Evaluation for Raw Material Changes of Passive Medical Devices

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In order to strengthen the supervision and guidance of medical device product registration and further improve the quality of registration review, the National Medical Products Administration has formulated the Guidance on the Evaluation for Changes in Raw Materials of Passive Medical Device Products. Now, it is hereby published.

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Attachment: Guidance on the Evaluation for Raw Material Changes of Passive Medical Devices

National Medical Products Administration

May 13, 2020

Attachment

Guidance on the Evaluation for Raw Material Changes of Passive Medical Devices

After the medical devices are approved and marketed, the registrant often needs to change the production equipment, raw materials, production process, inspection methods and quality control standards of these devices to further improve the product quality, meet the requirements of laws and regulations and standards, or improve the supply chain for other reasons. According to the medical device production quality management system requirements, when the changes in selected material, part or product function may affect the safety and effectiveness of medical device, any risks possibly caused by such changes should be evaluated and reduced by measures taken, if necessary, to an acceptable level in accordance with relevant laws and regulations.

The registrant's establishment of effective change control procedure is the key to ensure the continuous improvement of production management system for realization of production of high-quality products, and is also an important link in the quality management system of medical devices. In general, the change control procedures include the change identification, its initiation, analysis, review, verification, validation, approval and implementation. Among them, the analysis, verification and/or validation and review of the changed content are works that the enterprise shall focus on.

Since the raw material is an important carrier for medical devices to achieve their expected functions and is also an important guarantee for their safety and effectiveness, the change control of raw materials of medical devices has been of particular importance in various changes. Therefore, when the raw materials used in the production of the product change, the registrant shall fully evaluate the possible impact of the raw material change on the final medical device product so as to reduce the risk caused by the change to an acceptable range, and assess whether the registration approval is required based on the regulatory requirements.

The Guidance aims at providing a systematic document with guiding significance for risk analysis of raw material change in passive medical devices. It can be used to guide both the registrant in standardizing the R&D, registration application and quality control of relevant products and the regulators in the technical review of registration applications caused by changes in relevant passive medical device raw materials.

The Guidance is a general evaluation process for raw material change of passive medical device products. The registrant should enrich and detail the contents of registration submission based on the characteristics of specific products, and determine whether the related specific contents apply or not based on the characteristics of specific products. If not, the reasons and the corresponding scientific basis should be elaborated in detail. If it is not applicable, the reason and corresponding scientific basis shall be elaborated in detail.