FDA Guidance U.S. vs. China: What are the Differences

Mudi Geng

Intro

- The National Medical Products Administration (NMPA), also known as CFDA, has issued draft Guidance on the application of HFE and usability engineering to medical devices in China.
- The NMPA has recently revised their Guidance document, which is currently under final review and is expected to be published and implemented in mid-2023.
- As such, it is important to compare and contrast the Guidance provided by the NMPA with by U.S FDA to better understand and meet their expectations.

Highlight Differences

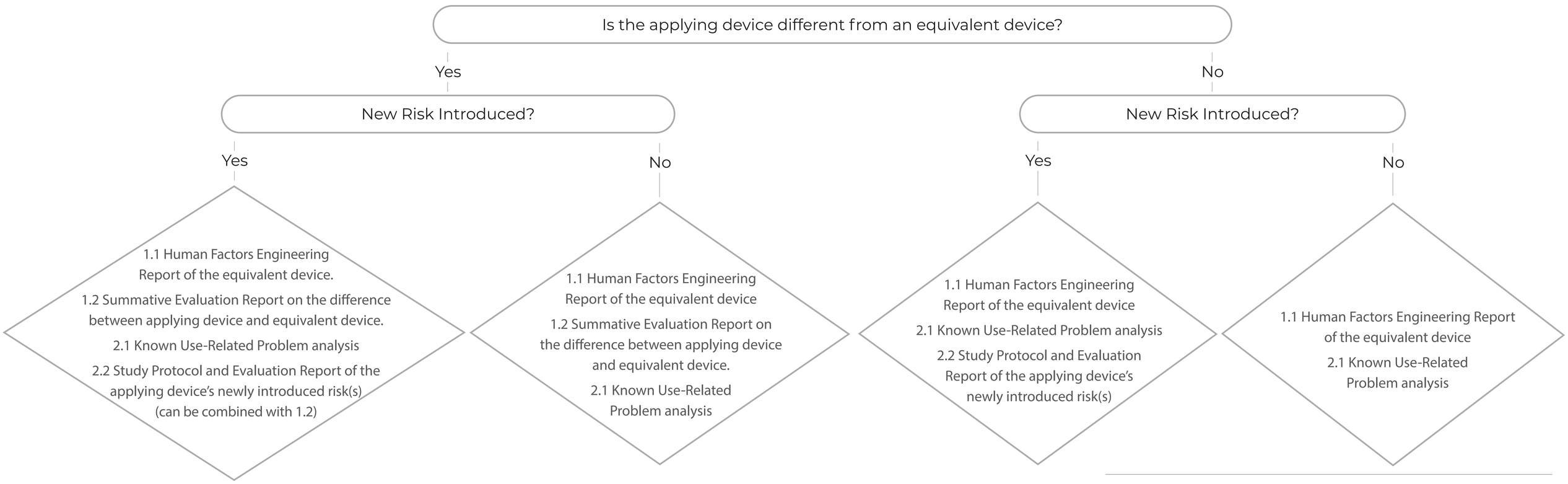
	US FDA	NMPA (CFDA)
Location	For the results of the Human Factors Validation Testing (a.k.a Summative Evaluation) to demonstrate safe and effective use by users in the United States, **the participants in the testing should reside in the US.**	**The Summative Evaluation should be conducted in China** • unless the manufacturer can provide detailed data demonstrating that differences between domestic and foreign context would not significantly impact the result.
Device Scope	Class I, II, and III	Only Class II and III
Task to Study	The Human Factors Validation Testing should **include all critical tasks** identified in the preliminary analyses and evaluations.	Emphasis on Critical Tasks, while also considering **frequent tasks and urgent tasks** (i.e., frequent tasks are the tasks that user performs frequently, and urgent tasks are the tasks that require users' action immediately).
Equivalence	Based on Predicate Device: • has the same intended use as the predicate; and • has the same technological characteristics as the predicate; OR • has the same intended use as the predicate • has different technological characteristics and does not raise different questions of safety and effectiveness • the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.	Equivalent Device: Provide the device has similar: • intended use (s) • user profile (s) • use environment (s) • tasks • user interface to a registered existing device in China.

Regulatory path for new devices is currently identical for FDA and CFDA

This guidance is based on international standards such as ISO 60601, IEC 62366, ANSI/AAMI HE75, and the FDA's guidance.

Flowchart illustrating a risk-based approach to determine the HF Submission Documents

The CFDA's Decision Tree



Direct Translation from CFDA's Guidance