Linux:

Adv -> For medical device developers, Wind River support of the Yocto Project means they have the best of both worlds: an industry standard platform that provides core functionality while remaining open to new innovations, plus the added value of a commercial vendor with deep expertise not only in Linux but also in high reliability, life-critical embedded systems. While the Yocto Project only integrates bug fixes for versions 6 months old, Wind River offers a much longer support timeline.

Challenges ->

The networking of what were once standalone medical devices is becoming increasingly common—for example, monitors in patients’ rooms that feed data directly into a centralized monitor in a nurse’s station. If Linux is being used in a medical device designed to be connected to a network, whether wired or wireless, the FDA’s guidance on cybersecurity applies. Simply stated, networks remain vulnerable to hacking, and the manufacturer must have a maintenance plan in place to deal with any networking vulnerabilities.

1. From Medical Domain, Linux is considered as a SOUP - IEC 62304, paragraph 3.29
2. Change Management - IEC 62304, paragraph 5.1.1 software development plan must address “software configuration and change management, including SOUP configuration items and software used to support development”.
3. Software risk management planning - IEC 62304, paragraph 5.1.7 With Linux, risk analysis would need to be produced by the development organization, and it is not clear how it could be produced without a failure rate figure being available.

All fault reports in the file system, communications stacks, drivers, etc. would also have to be analyzed.

1. The functional safety requirements would have to be defined. Someone would then have to carry out the necessary validation to ensure that the Linux OS complies with these requirements. IEC 62304, paragraph 5.3.3
2. Published SOUP anomaly lists - IEC 62304, paragraph 6.1

TIR80002, paragraph 3.4.1:

1. Responsibility for SOUP - IEC 62304, paragraph B.1.2
2. Failure modes of SOUP - TIR80002, paragraph 6.2.3 The higher the potential risks of the medical device, the more closely potential failure modes of SOUP should be analyzed and risk control measures identified.
3. Removing unnecessary SOUP components - TIR80002, section 9
4. Failure modes and frequency of SOUP - ISO 14971, paragraph 4.3
5. Identifying safety-related aspects of SOUP architecture - TIR80002, table C.1