



GS Yuasa Energy Solutions Inc.

Policy On Use Of Batteries In Medical Devices

GS Yuasa Energy Solutions Inc. (GYES) prohibits the use of its batteries in life-supporting or life-sustaining devices.

“Life-supporting and life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.” (Defined by the US Federal Food and Drug Administration, [CFR - Code of Federal Regulations Title 21 \(fda.gov\)](#))

In general, GYES’s prohibition for use of its batteries falls under medical devices that are required to comply with 510(k) requirements within Class I, Class II and Class III. Currently, medical devices exempt from 510(k) requirements in Class I and Class II, are generally accepted medical devices allowed to use GS Yuasa batteries. Exemptions of 510(k): [Medical Device Exemptions 510\(k\) and GMP Requirements \(fda.gov\)](#)

Approval for use of GS Yuasa batteries must be specifically granted by GYES, in writing, when considering life-supporting or life-sustaining medical device applications.

Clients wishing to use GS Yuasa batteries, including but not limited to product families NP, NPX, NPY, PWL, PYL, and SWU, in medical devices not exempt from 510(k) requirements should contact their local sales representative.

GS Yuasa accepts no liability for use of its batteries in any unapproved medical devices that does not comply with this statement.