【Flow Chart: Steps to Importing Medical Device-Class Ⅱ】

1. Finalize product to be imported

2.Prepare information of product

By Manufacturer, including specification with the international classification, efficacy, the way of use, and manual of the product.

NG/Revisable

3.Check classification of product

By Medilex, conduct checking classification , JMDN name, Certification Standards, Basic Requirement Standard and JIS, and inquiry for compliance of certification standard to registered certification body (JPY50,000 /product)

NG/No Revise

NG/Revisable

4. Registration of Foreign Manufacturer

By Medilex, apply registration of foreign manufacturer to PMDA
（Fee to PMDA:JPY90,000/manufacturer）

5. Specification Testing

Request to registered certification body .
Test item depends on product and Certification Standards . The data required for test must be provided by manufacturer.

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6. Application

By Medilex, apply to registered certification body.
Documents for submission：Application form, STED, attached reference etc.,
After application form accepted by the body, QMS compliance review will be conducted for QMS compliance product .

7. Start Import!

CERTIFIED

Import Given Up...

Rejection