Guidance on Evaluation of the Devices for Physical Function Recovery

1. Introduction

Robotic devices have been used in the field of rehabilitation medicine for restoration of physical function all over the world. To put such robotic technology, an area of expertise for Japan, to the practice use and to make it widely available for patients, it is necessary to evaluate the safety and efficacy of the devices by newly developed technology and related researches.

The proposed goals for a new device in the present guidance are to show (1) the accuracy, reproducibility, and utility of the devices in clinical situation of rehabilitation practice, or (2) reduction of the workload of therapists and other health care workers at least, through accumulating the knowledge on physical functions, which have traditionally depended upon the skill of well-trained therapists. The efficiency of the devices should be fine-controlled along with their working theory, and provide data-based quantitative performance.

This guidance provides a list of points to evaluate the safety and efficacy of the robotic devices based on scientific evidences.

2. Scope

This guidance applies to devices, including both hardware and software, designed for physical functional restoration.

This guidance is related to the preceding one about the devices for nerve function modulation (Attachment 2, Notification 1215 No. 1 of the Director of Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated December 15, 2010) to some extent. The target devices of this guidance are, however, those that modulate motor output by a force of actuator with sensing the surrounding environment and the target subject, and are eventually expected to improve physical functions of the subject, mainly motor control of the extremities and trunk.

In this guidance for physical function recovery, devices are defined as one to regulate their output action on physical activities according to the basic working theory, and to be used in living environment, including home, hospitals and healthcare facilities, in order to restore physical/cognitive functions and body structure, and eventually to improve patients' activities of daily living and social participation.

If it is difficult to determine whether a device to be developed is to be classified as a so-called "medical device" or not, it will be advised to consult with the Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare.

3. Role of This Guidance

Considering the fact that development of medical devices is totally dependent upon technological advances rapidly occurring in this area, this guidance is designed to provide not a comprehensive list of points to consider but those from the current knowledge. Therefore, it should be revised as technological innovation progresses and relating knowledge accumulates, and it is recognized as temporary guiding principles to help for the understanding of what information may be included in application documents for approval at the moment. For the evaluation of a specific product, it is necessary to show a thorough explanation of the characteristics of the product and to provide the data in scientifically rational method. It is also recommended that other relevant guidelines from both Japan and overseas should be referred in addition to this guidance.

4. Points to Consider in Evaluation

(1) Basic points

1) Specify the background of development, product specifications, usage in Japan and other countries, design and principle of the device operation, mechanism of action involved in the performance and efficacy, and intended use (including function and capability), etc.
2) Conduct risk assessment considering the installation site, operation of the device and other conditions to specify points to be considered in reference to the following items:

(a) Installation
- Weight
- Size
- Measures to prevent the device from falling off
- Load on contact site of the body with the device (e.g., compression, dislocation, or burn)

(b) Noise and vibration from the device

(c) Requirements for and details of maintenance/inspection
(d) Requirements for and details of training programs
(e) Safety measures for power units and drive units (e.g., requirements for stand-by power units, load on the drive control unit, maximum continuous operation time, and the time required for putting the device on the patient)
(f) Environmental measures (e.g., electromagnetic waves and temperature)
(g) operating environment (e.g., hospital, health care facility, or home)

(2) Non-clinical studies

Evaluate appropriately the performance and safety of the device for the following:

1) Performance evaluation

Provide specific data on each of the relevant items in the following:

(a) Performance of moving parts
- Type of drive system (e.g., active system or passive system)
- Type of control system (e.g., force control, position control, impedance control, compliance control, and display control)
- Back-drivability (e.g., driving force transmission mechanism between gripper and actuator)
- Motion accuracy (e.g., positional/spatial precision, temporal precision [including time delay], reproducibility, and their validation methods)
- Structure and function of sensors (e.g., position sensor, angle sensor, and biosignal sensor)
- Validity of precision (e.g., correlation with operation precision required for the patients)
- Working space and motion speed
- Output of actuator, etc. (including upper limit)
- Degrees of freedom of motion
- Spatial arrangement of the mechanism (e.g., interference with other devices, users, and the patient)

(b) Display of the device operating status
(c) Durability (including anticorrosion performance and pyrogenic tolerance)
(d) Software life-cycle management
(e) Self-checking function (including validation of operation precision mentioned above)

2) Safety and quality evaluation

Apply the following points for design control as needed:

(a) General requirements
- Electrical safety
- Mechanical safety
- Biological safety
- Quality management
- Risk management

(b) Specifications (including drive unit)
- Design requirements (user, specification, regulations, and standards)
- Input and output (e.g., type, method, and instruments)
- Usability
- Start-up, interruption, and termination

(c) Development/design plan
- Development process (including risk assessment)

(d) Documentation
- Documents for users (e.g., Devices's principle of operation, operation/maintenance manual)

(e) Type, structure, and validity of safety mechanism/control
- Alarm (e.g., type and display) (ref., IEC60601-1-8, etc.)
- Emergency stop function (ref., ISO10218-1, ISO13850, JIS T2304, etc.)
- Emergency stop device and its structure
- Conditions for emergency stop (e.g., malfunction against user's intention, and activation of safety mechanism)
- State of the device during emergency stop
- Ensuring the safety of patients and medical workers during emergency stop (e.g., maintenance of the device posture)
- Ease of restarting the device after emergency stop

- Preventive measures against malfunction (user interface)
- Measures to prevent patients or medical workers from falling over
- Failure to safety
- Fool-proofing

(f) Robustness of software control

(g) Device-specific risk management

- Normal but unexpected actions
- Unexpected actions by humans, animals, and other object under the usage conditions
- Unexpected travel surface condition (e.g., mobile robot)
- Uncertainty of objects to be handled (e.g., for mobile servant robots)
- Compatibility with anatomical structures and variations of the human body (e.g., for physical assistant robots)
- Other necessary items

(3) Clinical studies (ref., PFSB/ELD/OMDE Notification No. 0804001, dated August 4, 2008)

1) Necessity of clinical studies

If the clinical efficacy and safety of a medical device cannot be evaluated only by using the results of non-clinical studies such as performance tests or existing literatures, it is required to conduct a clinical study and submit documents on the results of it. If the intended use, performance, structure, and other features of the medical device are distinctly different from those of existing medical devices, documents on the results of clinical studies are, in principle, required to be submitted.

2) Efficacy and safety evaluation

A clinical study is to be conducted on devices for which the performance, safety, and quality were validated in non-clinical study.

In conducting a clinical study, firstly demonstrate that the target function of activity is sufficiently expected to be recovered or supported, develop an action plan, and evaluate the efficiency and safety of the device, taking into consideration the points given below. Also, provide information about the expected environment of devices.

(a) Characteristics of activity function recovery devices

i) To demonstrate the efficacy of a medical intervention technology, a control group is necessary as well as an intervention group. If a control group cannot be set, the data of the natural course after the onset of a target disease need to be obtained. The efficacy may be evaluated on the basis of improvement in the expected natural course of the disease after onset. In addition, a pilot study may be conducted.

ii) In the evaluation of activity function, use qualitative or quantitative methods of movement patterns, or quantitative methods of time required for completing a movement, etc. Data on quantitative evaluation before and after intervention are useful as improvement indicators. The evaluation criteria must be validated for a certain level of sensitivity, reproducibility, and feasibility.

iii) As upper-extremity motor function tests, there are the simple test for evaluating hand function (STEF), manual function test (MFT), Fugl-Meyer Assessment (FMA), Wolf Motor Function Test (WMFT), etc. As balance function tests, there are the functional reach test (FRT), stabilometry, timed up and go test (TUG), Berg Balance Scale (BBS), etc. As locomotion tests, there are the 10-meter maximum walking speed, 6-minute walk test, and physiological cost index, etc. In addition, surface electromyography or a three-dimensional motion analysis may be used to compare the data before and after intervention.

iv) It is important to take into account the changes in activities of daily living (ADL) before and after intervention. Use the Barthel Index, Function Independence Measure (FIM), etc. It is also important to determine whether or not the quality of life (QOL) is improved after intervention using such as EuroQol (EQ-5D), SF-36, visual analog scale (VAS), etc.

(b) Evaluation of reducing burden of medical workers

The efficacy evaluation of activity function recovery devices has two aspects: the aspect that the inherent benefit of the device itself and the other aspect that such devices may facilitate to reduce burden of therapists and/or other medical workers engaged in rehabilitation. It is necessary to demonstrate clearly that activity function recovery devices enable medical workers to provide patients with adequate training, which cannot be performed by medical staff alone, considering the problem of the time required for putting on the device, and how

the devices lead to improvement in movement and activities.

It is also important to demonstrate explicitly to what extent the activity function recovery device reduces the burden of medical workers, and to evaluate the improvement in QOL after intervention using EQ-5D, SF-36, VAS or other scales.

3) Sample size

The sample size for a clinical study shall be determined to be one that is appropriate for an efficacy and safety evaluation of the target device in view of the objective and primary endpoint of the study, and based on the scientific evidence. For special cases, such as orphan medical devices for which the number of patients with the indicated disease is very small, develop an appropriate study design with a sample size that enables the study to be performed and the results to be evaluated, considering the situation.

If a control group is to be set, note that the sample size is to be determined statistically.

Reliable data from overseas studies may be used in attachments to the application for approval in some cases. Sufficient consideration is, however, necessary to determine whether or not the clinical evaluation can be carried out only with such data.

4) Evaluation period

In conducting a clinical study, evaluate at appropriate times according to the characteristics of subjects. If the device is to be used for a long time after the study period, consider to conduct post-marketing surveillance.