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Innovative Medical

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JIMURENRAKU
2022 Jan. 26

Each (TODOFUKEN (Local Government) / City that has health center / Special district) Hygiene administration department (bureau) pharmaceutical work

Ministry of Health, Labor and Welfare, Pharmaceutical and Living Hygiene Bureau, Monitoring and Guidance, Narcotics Countermeasures Division

About the consultation procedure at the "Consultation window for medical device applicability of the program"

For consultation on the applicability of standalone program as medical device, refers to "Consultation on the applicability of medical devices in the program" (MHLW, Ministry of Health, Labor and Welfare, Pharmaceutical and Living Hygiene Bureau Monitoring and Guidance, Narcotics Countermeasures Division Office Contact). From April 1, 2021, we contacted the Ministry of Health, Labor and Welfare's Pharmaceutical and Living Hygiene Bureau Monitoring and Guidance and Narcotics Countermeasures Division's "Medical Device Applicability Consultation Window for Programs" (hereinafter referred to as "Consultation Window") to accept consultations.
Please understand that we have decided to set up the consultation procedure to the consultation desk as follows. Please be aware of the above and the people concerned in your jurisdiction and related organizations.

Note

1 Notes for consultation

（1） "Guidelines for Program Medical Device Applicability"(2021 March 31st, YAKUSEIKISHINHATSU 0331 No. 1, YAKUSEIKANMAHATSU No. 0331 No. 15, Ministry of Health, Labor and Welfare, Medical Device Examination and Management Division, Monitoring and Guidance, Narcotics Countermeasures Division Notification. After confirming the "Guidelines"). Please apply with materials described below.

（2） As a general rule, consultation should be conducted by e-mail. The Monitoring and Guidance / Narcotics Countermeasures Division may request additional materials.

（3） After the consultation starts, if there is no response from the applicant for a certain period to the inquiries from the Monitoring and Guidance / Narcotics Countermeasures Division. If no response is obtained from the qpplicant even after (approximately one month) has passed, it may be treated as termination of counseling.

（4） At that time, the submitted materials should be discarded.

（5） The submitted materials should be shared with the Ministry of Health, Labor and Welfare and the relevant departments of the Pharmaceuticals and Medical Devices Agency if the Monitoring and Guidance and Narcotics Countermeasures Division deems them necessary for applicability judgment.

2 Notes for filling out the consultation form

(1) Fill out this form for each function, even for one program. Example) ○○ program (electrocardiogram measurement function, health record function, meal record function)

→ 1 sheet for ECG measurement function, 1 sheet for health record function, 1 sheet for meal record function

(2) The user of the program function assumed by the counselor is an individual / home (Excluding those used by individuals under the control of medical personnel.) If it is the form of Attachment 1, and if it is medical personnel (including those used by individuals under the control of medical personnel), Attachment 2 Fill out the form.

(3) When filling out this form, please refer to the guideline "Determining Flow Chart." Please check "Q & A" and use it as a reference.

3 Submission of materials related to products

(1) When applying for consultation, in addition to the completed consultation form, attach materials related to the explanation of the functions of the product, the calculation algorithm of the result, the image of the product display screen, the advertisement of the product, etc. The submitted materials will not be published.

(2) Please do not attach the company profile to minimize the submitted materials.

4 Publication of judgment cases on the Ministry of Health, Labor and Welfare website

Summary of judgment cases at the consultation desk will be summarized in a database and published in principle on the Ministry of Health, Labor and Welfare website. However, if there is a request from a company, it will not be announced.

Posting
pagehttps://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000179749_00004.html

Attachment

Form 1: Applicability consultation form for program medical device (Programs used by individuals)

Applicant for consultation	Company Name: Contact information (phone number, email address):
Applicable to medical devices. Assumption of the consultant	□ 1Medical device applicable □ 2 Not applicable to medical devices
Product name / Intended for use	
Function	
Product Summary	
Acceptance of publication of consultation summary (In general, should be accept.)	If you do not want to the publicity, write reason:

1	Purpose	Intended for diagnosis, treatment and prevention of diseases?		1 YES		2 NO→ 2 to "Target user"
	Answer only when you judged YES for the above.	If there is a medical device that performs the same treatment, does the device fall under Class I or II or higher?		1 Class I (Product name:)		2 Class II or higher (Product name:)
	Answer when the above is unknown or the same medical device is not available.	When you judge based on GHTF rules (* 1), your medical device program it equivalents to Class II or higher?		1 YES		2 NO
2	Target user	Is it a product for individuals / homes? For healthcare professionals (* 2) product?		1 individual		2 Healthcare professional (* 2) → If 1 is not circled, use Form 2.
3	About the function and purpose of the program (Answer only when you judge NO in "1 purpose")					
	(1) Is it only to display data on screen, store, and transfer?			1 YES		2 NO→ To (2)
	(2) Is it for exercise purpose and not for medical care / health management?			1 YES		2 NO→ To (3)
	(3) is it for only providing information to users? (* 3)			1 YES		2 NO→ To (4)
	(4) Data processing not for diagnosis, treatment, and prevention?			1 YES		2 NO→ To (5)

	(5) Do you want to display expected disease based on the input information?		1 YES		2 NO→ To (6)
	(6) Based on the GHTF rule, is it Class II or higher?		1 YES		2 NO
4	Have you confirmed "Guidelines for program medical device applicability"?		1 YES		2 NO
	As a result of checking the flowchart of "Guideline for medical device applicability of the program", how did the company make the decision? Please describe what are the points on you question?				

* 1 About classification, when making a decision based on the GHTF rules, refer to "Revision of classification rules for highly controlled medical devices, controlled medical devices and general medical devices" (2013, May 10, YAKUSOYKUHATU 0510, No. 8, Notice of Director, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare) for your judgment.

* 2 Includes those used by individuals under the control of medical personnel.

* 3 When providing information, if the grounds for judgment are not shown to the user, or if the material for grounds for judgment are difficult for users who are not healthcare worker to understand, mark ○ in NO.

Attachment

Form 2: Applicability consultation form for program medical devices (Program used by medical personnel)

Applicant for consultation	Company Name: Contact information (phone number, email address):
Applicable to medical devices. Assumption of the consultant	□ 1Medical device applicable □ 2 Not applicable to medical devices
Product name / Intended for use	
Function	
Product Summary	
Acceptance of publication of consultation summary (In general, should be accept.)	If you do not want to the publicity, write reason:

1	Purpose	Intended for diagnosis, treatment and prevention of diseases?		1 YES		2 NO →2 to Target User
	Answer only when you judged YES for the above.	If there is a medical device that performs the same treatment, does the device fall under Class I or II or higher?		1 Class I (Product name:)		2 Class II or higher (Product name:)
	Answer when the above is unknown or the same medical device is not available.	When you judge based on GHTF rules (* 1), your medical device program it equivalents to Class II or higher?		1 YES		2 NO
2	Target user	Is it a product for individuals / homes? For healthcare professionals (* 2) product?		1 individual → If 2 is not circled, use Form 1.		2 Healthcare professionals (* 2)
3	About the function and purpose of the program (Answer only when you judge NO in “1 purpose”)					
	(1) Is it only for providing information, that is not for medical judgment for medical personnel, patients, etc.?			1 YES		2 NO→ To (2)
	(2) Is it for in-hospital work support or maintenance?			1 YES		2 NO→ To (3)
	(3) Is it only for data storage and data transfer?			1 YES		2 NO→ To (4)
	(4) Day for purposes other than diagnosis, treatment, and prevention Do you only want to graph the data and display the image?			1 YES		2 NO→ To (5)

	(5) Data processing for the purposes of diagnosis, treatment, and prevention?		1 YES		2 NO→ To (6)
	(6) Processing according to diagnosis / treatment guidelines, etc.? (* 3)		1 YES		2 NO→ To (7)
	(7) Do you want to display expected disease based on the input information?		1 YES		2 NO→ To (8)
	(8) Based on the GHTF rule, is it Class II or higher?		1 YES		2 NO
4	Have you confirmed "Guidelines for program medical device applicability"?		1 YES		2 NO
	As a result of checking the flowchart of "Guideline for medical device applicability of the program", how did the company make the decision? Please describe what are the points on you question?				

* 1 About classification, when making a decision based on the GHTF rules, refer to "Revision of classification rules for highly controlled medical devices, controlled medical devices and general medical devices" (2013, May 10, YAKUSOYKUHATU 0510, No. 8, Notice of Director, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labor and Welfare) for your judgment.

* 2 Includes those used by individuals under the control of medical personnel.

* 3 When providing information, if the grounds for judgment are not shown, mark ○ in NO.