PSEHB/MDED
Notification No. 0831 (2)
August 31, 2020

To: Directors of Prefectural Health Departments (Bureaus)

Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)

Handling of the Conditional Approval of Medical Devices and In Vitro Diagnostic Pharmaceuticals

For innovative medical devices for diseases that have a significant influence on life and no existing effective treatments, there will be great difficulty in collecting the clinical data necessary for approval applications for reasons such as the prolongation of clinical development due to the small number of patients and considerable time required for the implementation of clinical trials. For these reasons, based on "Conditional Early Approval System for Innovative Medical Device Products (Fast-Break Scheme)" (PSEHB/MDED Notification No. 0731-1, issued by the Director of the Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as "MHLW"), dated July 31, 2017) (hereinafter referred to as the "previous notification"), we have been planning post-marketing risk management from the development stage, including setting of conditions for use and post-marketing data collection, and promoting early practical use of medical devices with a balance between risks and benefits, on the premise that we will take strict measures against risks that will not be revealed by limited clinical data obtained before application. We have now clarified this legally as a system under the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960, hereinafter referred to as the "Act") as amended by the Act for Partial Amendment of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019), which approves Article 23-2-5, Paragraph 1 or Paragraph 15 of the Act with conditions pursuant to the provisions of Paragraph 12 of the same Article (hereinafter referred to as the "Conditional Approval System for Medical Devices, etc."), and we will handle it as described below. We appreciate your understanding and consideration in disseminating this information to relevant organizations and institutions in your jurisdiction.

Applications for marketing approval or applications for partial changes in approved items for marketing based on previous notifications, irrespective of this notification, the notified medical device shall be handled as before.

Notice

1. Target product

A medical device or in vitro diagnostics (hereinafter referred to as “IVD”) that meets all of the requirements shown in the following (1) or (2).).

(1) Type 1

(a) The target should be a disease that has a significant impact on life or a disease with irreversible progression that has a significant impact on daily life.

(b) There are no existing therapies, preventive methods, or diagnostic methods, or markedly higher efficacy or safety compared to existing therapies.

(c) The ability to present appropriate clinical data for certain evaluations.

(d) The applicant can reasonably explain that conducting a new clinical trial or clinical performance study is difficult.

(e) The applicant can prepare proper use guideline in close cooperation with related academic societies and concretely present a plan for the collection and evaluation of post-marketing data.

Points to consider for each requirement and for the description of the summary of eligibility for the conditional approval system for medical devices. (hereinafter referred to as “summary of eligibility”) are presented in Appendix 1.

(2) Type 2

(a) Medical devices intended for ablation or other physical functions to affect the structure or function of the human body or IVD considered to be of particularly high medical need.

(b) It is possible to present appropriate clinical data with certain extrapolability to assess the efficacy and safety of an expanded intended use that has not been directly assessed by existing clinical data.

(c) It can be rationally explained that its proper use can be ensured without conducting a new clinical trial or clinical performance study.

(d) The applicant can prepare proper use guideline in close cooperation with related academic societies and concretely present a plan for the collection and evaluation of post-marketing data.

Points to consider for each requirement and for the description and summary of eligibility are presented in Appendix 2.

2. Consultation on the application of the proposed system

(1) If you wish to apply for approval under this system, apply for the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) Pre-development consultation for medical devices or for IVD (hereinafter referred to as “pre-development consultation”). In this consultation, the applicant, the

MHLW, and PMDA will exchange opinions on whether the medical devices to be applied for will be eligible for this system, based on summary of eligibility in the attached form submitted by the applicant.

(2) Taking into account the exchange of opinions with the applicant, the MHLW and the PMDA will consider whether the product to be applied for will be eligible for this system, comprehensively taking into account the requirements shown in 1. (1) or (2) above. Additional information and materials necessary for judgment may be requested at this time. In addition, as necessary, the MHLW ask "Review Committee for Early Introduction of Medical Devices, etc. with High Medical Need" (hereinafter referred to as "Needs Review Committee") to evaluate the seriousness of the disease and the availability of alternative methods, and the consideration will be performed based on their evaluation.

If it is judged that this system is likely to be applied and it is allowed to proceed to "consultation on the necessity of a clinical study for medical devices" or evaluation consultation on a clinical performance study for IVD", the matter shall be described in the minutes for pre-development consultation. If it is impossible to judge whether the application of this system is appropriate by the time of finalization of the consultation minutes (within approximately 30 business days after face-to-face consultation), the MHLW and the PMDA shall notify the applicant.

(3) It may be determined that the product you plan to apply is eligible for this system without undergoing the pre-development consultation in 2. (1) and (2) in following cases; the prodct is designated as a medical device or a pharmaceutical for orphan diseases (hereinafter referred to as "medical devices, etc. for orphan diseases"), designated as a Sakigake medical device or a Sakigake IVD, designated as a specific-use medical device or a specific-use IVD, or designated as a medical device, etc. with high medical needs by the Needs Review Committee. In these cases, before applying for the pre-development consultation, please create the summary of eligibility in the attached format and consult with the Medical Devices Review and Management Division of the MHLW.

3. Procedures for preliminary consultation and approval application

(1) Consultation on the necessity of clinical trials for medical devices or evaluation consultation on clinical performance study for IVD'

If you plan to apply the products under this system without conducting new clinical trials or clinical performance studies, you should apply for the PMDA's "consultation on the necessity of clinical trials for medical devices" or "evaluation consultation of clinical performance studies for IVD" before submitting the application, to confirm whether the evaluation of available clinical data and the

draft content of the risk management plan for medical devices or IVD (hereinafter referred to as “medical device RMP”) are appropriate. In the consultation, with the medical expert present as necessary, the PMDA advises on whether the risk-benefit balance of clinical safety and efficacy can be appropriately evaluated based on the existing clinical data, draft proper use guideline, etc., considering the seriousness of the target disease, as well as on the contents of post-marketing risk management, data collection, etc. that are necessary to secure the appropriate use.

At the time of application for consultation, it shall be described in the Remarks column of the application form that consultation with the Medical Device Evaluation Division of the MHLW or pre-development consultation has already been conducted on the applicability of the conditional approval system and the consultation minutes in 2. (2) shall be attached. (If you have not received any consultation, the Medical Device Evaluation Division of the MHLW will contact you individually.)

(2) Approval application and review

i. At the time of making the approval application, a draft medical device RMP shall be attached as part of the documents on the results of clinical trials or clinical performance studies, and the fact that the product has already undergone consultation with the Medical Device Evaluation Division of the MHLW or pre-development consultation on the applicability of the conditional approval system, with the date/time and reception No. of consultation in 2. (2) and 3. (1) in the Remarks column of the application form. Extra attention shall be paid to the system development necessary for the QMS compliance review, since its application should be made promptly after the approval application.

ii. For the method of preparing a medical device RMP, see “Establishment and Publication of Risk Management Plan for Medical Devices and In Vitro Diagnostic Pharmaceuticals” (PSEHB/MDED Notification No. 0831-3 and PSEHB/SD Notification No. 0831-1 dated August 31, 2020 issued jointly by the Director of Medical Device Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW) and “Guidance on Risk Management of Medical Devices and In Vitro Diagnostic Pharmaceuticals” (PSEHB/MDED Notification No. 0831-4 and PSEHB/MDED Notification No. 0831-2 dated August 31, 2020 issued jointly by the Director of Medical Device Evaluation Division and the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW).

iii. In the approval review, the validity of the draft medical device RMP shall be confirmed, and the safety, efficacy, etc. shall be confirmed on the premise that the confirmed RMP contents will be appropriately implemented. The products subject to this system shall be subject to use-results evaluation in principle. The

implementation of post-marketing risk management, such as proper use guideline is secured by setting it as approval conditions based on Article 23, 2-5, Paragraph 12 of the Act.

4. Procedure after approval

(1) In principle, the medical device RMP shall be submitted to the PMDA by one month before the planned start of marketing. According to the RMP, post-marketing information shall be collected, information shall be provided to medical professionals and patients, and other necessary measures shall be taken to ensure the proper use of medical devices and to prevent health hazards.

(2) If data for use-results surveys is planned to collect through database information on medical case registration (registries) at related academic societies, it should be ensured that the necessary data can be verified upon the request of the MHLW and PMDA, and responsibilities for data management and use shall be clarified in advance.

(3) Reports of the use-results survey to the PMDA pursuant to the provisions of Article 23 Paragraph 6 (periodic report) should be made every year during the period of the use-results survey, since the product will be subject to the use-results evaluation specified in Article 23, Paragraph 2, Item 9 of the Act in principle. For periodic reporting, it should be considered to share the latest information with physicians, who use medical devices. For other use-results surveys, refer to related notifications such as “Handling of Drug Use-Results Evaluation Related to Marketing Approval of Medical Devices and In Vitro Diagnostic Pharmaceuticals” (PFSB/ELD Notification No.1121 No. 44 of November 21, 2014 issued by the Counselor of Minister’s Secretariat, MHLW (Evaluation and Licensing of Medical Device/Regenerative Medicine Product)).

(4) Consult the PMDA in advance when the contents of the post-marketing RMP including the proper use guideline are planned to be changed or when the treatment available medical facilities are planned to be expanded, based on the evaluation of use-results survey, post-marketing trends in the occurrence of malfunctions and/or accumulation of post-marketing data.

(5) It is desirable to sufficiently examine the plan for collection of post-marketing data and the method for utilization of the collected data by using the consultation with the PMDA as necessary so that the data collected from the use-results survey, post-marketing clinical study, registry, etc. of medical devices subject to this system will be useful not only for reviewing the contents of medical device RMP, but also for future improvement of medical devices, and future approval

application.

5. Points to consider

(1) If the product is thought to be eligible for “Handling of Medical Devices for Medical Doctors for Off-label Use” (HPB/RDD Notification No. 0522001/PFSB/ELD Notification No. 0522001 dated May 22, 2006, jointly issued by the Director of Research and Development Division, Health Policy Bureau and the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW), it may be appropriate to make an approval application regardless of this system, so consult the Medical Device Evaluation Division, MHLW individually.

(2) If the product is thought to be eligible for “Clarification of Handling of Clinical Study Data on Medical Devices for Rare Diseases” (PFSB/ELD/OMDE Notification No. 0329-1 dated March 29, 2013, issued by the Director of Office of Medical Device Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW) or if the clinical efficacy and safety of a product under development can be evaluated by the results of non-clinical studies such as performance studies and animal studies, existing literature, etc., the use of face-to-face consultation with the PMDA should be considered first. Then, the use of this system shall be considered as necessary.

6. Effective date

This notification shall come into effect from September 1, 2020.

Annex 1

Points to consider for each requirement subject to the conditional approval system for medical devices. (Type 1) and for description of a summary of eligibility

i. Requirement A

Briefly describe the outline of the target disease, patient background, number of target patients for the product to be applied for, etc., and provide the source of the information and supporting data.

ii. Requirement B

Present the presence or absence of existing treatment methods for the target disease, and if treatment methods exist, provide the details (the procedure, medical devices used, clinical data, etc.) and associated problems. Additionally, describe how the proposed application product is superior to the existing medical devices. Articles, clinical practice guidelines in Japan and overseas, medical books, etc. which serve as the rationale for the description shall be listed as references, and their copies shall be attached.

If any similar product is being developed in Japan, explain its outline to the extent possible.

iii. Requirement C

The summary of available results of clinical studies, clinical performance studies, etc. shall be described, and the fact that clinical efficacy is shown and anticipated risks are acceptable shall be explained. The results of exploratory clinical trials, overseas clinical studies, clinical performance studies, etc., are expected, but data such as Advanced Medical Care and clinical research, literature information, etc., can also be used. In principle, data on individual medical cases are available. If there are any articles or other documents that can be used as the basis for the content of the description, please list them as sources and attach a copy of the relevant material. Explain the standards and ethical guidelines referred to in the conduct of the study and any measures taken to ensure data reliability.

If there is any ongoing clinical study or clinical performance study, describe the outline.

v. Requirement D

Describe specifically the development status to date and the reasons for the difficulty of conducting clinical or clinical performance studies. If there is any opinion from related academic societies, please attach it. Explain the period considered necessary for a new clinical trials or clinical performance study if it is assumed to be conducted,.

iv. Requirement E

It shall be possible to prepare appropriate proper use guideline for the product to be applied in cooperation with related academic societies. In the summary of eligibility, briefly describe as much as possible the contents of the draft of the proper use guideline, progress of its preparation, plan for collection and evaluation of post-marketing data, etc.

The draft proper use guideline may include requirements for physicians and medical institutions, handling methods for medical cases and complications requiring special attention for use, implementation plans such as lectures, training, and proctoring, and concepts for expanding treatment available medical facilities. The related academic societies are the subcommittees of the Japanese Association of Medical Sciences or the Japanese Association for Dental Science (hereinafter referred to as "subcommittees") is considered, and in principle, academic societies deeply related to the use of the product to be applied and the treatment of complications that may occur when using the product are involved. If an academic society other than the subcommittee takes the lead, note the relationship with the subcommittee, and it should be explained that the cooperation of the subcommittee is available in the preparation of proper use guideline if necessary. In addition, contact information of persons in charge of academic societies shall be added.

The proposed plan for post-marketing data collection and evaluation shall describe the purpose and method of data collection, method and timing of data evaluation, method of consideration when expanding the treatment available medical facilities based on the draft proper use guideline, method of providing the latest information on the collected use results, malfunctions, etc. to physicians using the medical device.

If possible, a draft medical device RMP (including a draft standard for proper use guideline and a plan for use-results surveys) shall be attached.

vi Other

If the product under development has been designated as a medical device for orphan diseases, a Sakigake medical device or a Sakigake IVD, a specific-use medical device or IVD, or selected as a medical device or IVD with high medical needs by Needs Review Committee, state this in the Remarks column.

Annex 2

Points to consider for each requirement subject to the conditional approval system for medical devices. (Type 2) and for description of a summary of eligibility

i. Requirement A

Briefly describe the outline of the shape, structure, principle etc., the outline of target disease, patient background, number of target patients, etc., of the product to be applied for, and provide the source of the information and supporting data.

ii. Requirement B

The summary of available results of clinical studies, clinical performance studies, etc. shall be described, and the fact that clinical efficacy is shown and anticipated risks are acceptable shall be explained. The results of exploratory clinical trials, overseas clinical studies, clinical performance studies, etc., are expected, but data such as Advanced Medical Care and clinical research, literature information, etc., can also be used. In principle, data on individual medical cases shall be available. If there are any articles or other documents that can be used as the basis for the content of the description, please list them as references and their copies shall be attached. Explain the standards and ethical guidelines referred to in the conduct of the study and any measures taken to ensure data reliability.

If there is any ongoing clinical study or clinical performance study, describe the outline.

iii. Requirement C

Describe specifically the development status so far and the reason why it is considered possible to secure proper use without conducting a new clinical or clinical performance study. If there is any opinion from related academic societies regarding the assurance of proper use, please attach it.

iv. Requirement D

It shall be possible to prepare proper use guideline for the product to be applied in cooperation with related academic societies. In the summary of eligibility, briefly describe as much as possible the contents of the draft proper use guideline, progress of preparation, plan for collection and evaluation of post-marketing data, etc.

The draft proper use guideline may include requirements for physicians and medical institutions, handling methods for medical cases and complications requiring special attention for use, implementation plans such as lectures, training, and proctoring, and concepts for expanding treatment available medical facilities. The related academic societies are the subcommittees of the Japanese Association of Medical Sciences or the Japanese Association for Dental Science (hereinafter

referred to as “subcommittees”) is considered, and in principle, academic societies deeply related to the use of the product to be applied and the treatment of complications that may occur when using the product are involved. If an academic society other than the subcommittee takes the lead, note the relationship with the subcommittee, and it should be explained that the cooperation of the subcommittee is available in the preparation of proper use guideline if necessary. In addition, contact information of persons in charge of academic societies shall be added.

The proposed plan for post-marketing data collection and evaluation shall describe the purpose and method of data collection, method and timing of data evaluation, method of consideration when expanding the treatment available medical facilities based on the draft proper use guideline, method of providing the latest information on the collected use results, malfunctions, etc. to physicians. using the medical device.

If possible, a draft RMP for medical devices, etc. (including a draft proper use guideline and a plan for use-results surveys).) shall be attached.

v. Other

If the product under development has been designated as a medical device for rare diseases, a Sakigake medical device or Sakigake IVD, a specific-use medical device or IVD, or selected as a medical device or IVD with high medical needs by the Needs Review Committee, state this in the Remarks column.

Attached Form 1

Summary of eligibility for Medical Device Conditional Approval System (Type 1)

<table>
<tr><td colspan="2">Name of the applicant</td><td></td></tr>
<tr><td rowspan="2">Name</td><td>Term name*1</td><td></td></tr>
<tr><td>Brand name*2</td><td></td></tr>
<tr><td colspan="2">Intended use or effects</td><td></td></tr>
<tr><td rowspan="2">Requirement A</td><td>The seriousness of the target disease</td><td>☐ A serious disease that significantly affects daily life
☐ Disease progression that significantly affects daily living</td></tr>
<tr><td colspan="2">(General information of target disease, etc.)</td></tr>
<tr><td rowspan="2">Requirement B</td><td>Existing therapies, etc.</td><td>☐ No existing therapy, etc.
☐ Efficacy or safety is expected to be markedly higher than those of existing treatment methods.</td></tr>
<tr><td colspan="2">(Differences from existing therapies, etc.)</td></tr>
<tr><td rowspan="2">Requirement C</td><td>Existing clinical data</td><td>☐ Clinical trials ☐ Clinical research
☐Literature ☐Other</td></tr>
<tr><td colspan="2">(Summary of study results suggesting efficacy, etc.)</td></tr>
<tr><td rowspan="2">Requirement D</td><td>Problems to conduct clinical trials</td><td></td></tr>
<tr><td colspan="2">(Status of development so far, reasons why it is difficult to conduct clinical studies, etc.)</td></tr>
<tr><td rowspan="2">Requirement E</td><td>Post-marketing risk management</td><td></td></tr>
<tr><td colspan="2">(Progress status of review of draft proper use guideline, etc. with related academic societies)</td></tr>
<tr><td>Remarks</td><td colspan="2">(Note: If the product has been selected as a medical device for orphan diseases or a medical device with high medical needs, state so.)</td></tr>
</table>

*1: If the nonproprietary name has not been determined, describe “New.”

*2: Enter if it has already been determined. If approved in Japan, enter the Japanese name. Otherwise, enter English. *If a nonproprietary name has not been determined, provide a tentative name.

(Other considerations)

1 Use the A4-sized form.

2 If a more detailed explanation is required, it is acceptable to attach it as an appendix.

3 These documents should be prepared under the assumption that they will be used as publication materials.

Attached Form 2

Summary of eligibility for In Vitro Diagnostics Conditional Approval System (Type 1)

<table>
<tr><td colspan="2">Name of the applicant</td><td></td></tr>
<tr><td rowspan="2">Name</td><td>Term name*1</td><td></td></tr>
<tr><td>Brand name*2</td><td></td></tr>
<tr><td colspan="2">Anticipated indications</td><td></td></tr>
<tr><td rowspan="2">Requirement A</td><td>The seriousness of the target disease</td><td>☐ A serious disease that significantly affects daily life
☐ Disease progression that significantly affects daily living</td></tr>
<tr><td colspan="2">(General information of target disease, etc.)</td></tr>
<tr><td rowspan="2">Requirement B</td><td>Existing therapies, etc.</td><td>☐ No existing therapy
☐ Efficacy or safety is expected to be markedly higher than those of existing diagnostic methods.</td></tr>
<tr><td colspan="2">(Differences from existing therapies, etc.)</td></tr>
<tr><td rowspan="2">Requirement C</td><td>Existing clinical data</td><td>☐ Clinical performance study ☐ Literature
☐ Other</td></tr>
<tr><td colspan="2">(Summary of performance study results suggesting efficacy, etc.)</td></tr>
<tr><td rowspan="2">Requirement D</td><td>Problems to conduct clinical performance studies</td><td></td></tr>
<tr><td colspan="2">(Status of development so far, reasons why it is difficult to conduct clinical performance studies, etc.)</td></tr>
<tr><td rowspan="2">Requirement E</td><td>Post-marketing risk management</td><td></td></tr>
<tr><td colspan="2">(Progress status of review of draft proper use guideline, etc. with related academic societies)</td></tr>
<tr><td>Remarks</td><td colspan="2">(Note: If the product has been selected as IVD for orphan diseases or selected as an IVD with high medical needs, state so.)</td></tr>
</table>

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*2: Enter if it has already been determined. If approved in Japan, enter the Japanese name. Otherwise, enter English. *If a nonproprietary name has not been determined, provide a tentative name.

(Other considerations)

1 Use the A4-sized form.

2 If a more detailed explanation is required, it is acceptable to attach it as an appendix.

3 These documents should be prepared under the assumption that they will be used as publication materials.

Attached Form 3

Summary of eligibility for Medical Device Conditional Approval System (Type 2)

<table>
<tr><td colspan="2">Name of the applicant</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Name</td><td>Term name※1</td><td colspan="2"></td></tr>
<tr><td>Brand name※2</td><td colspan="2"></td></tr>
<tr><td colspan="2">Intended use or effects</td><td colspan="2"></td></tr>
<tr><td rowspan="2">Requirement A</td><td>Target disease</td><td colspan="2">☐ It is intended to affect the structure or function of the human body via cauterization or other physical procedures.</td></tr>
<tr><td colspan="3">(General information of target disease, etc.)</td></tr>
<tr><td rowspan="2">Requirement B</td><td>Existing clinical data</td><td colspan="2">☐Clinical trial ☐Clinical research
☐Literature ☐Other</td></tr>
<tr><td colspan="3">(Summary of appropriate clinical data for evaluation with some extrapolation to efficacy and safety for the application range not directly evaluated in existing clinical data)</td></tr>
<tr><td rowspan="2">Requirement C</td><td>Validity of the application according to the target application range</td><td colspan="2">☐ The physical features of the product to be applied to allow evaluation of its efficacy and safety for the intended use or effect without conducting new clinical trials.</td></tr>
<tr><td colspan="3"></td></tr>
<tr><td rowspan="2">Requirement D</td><td>Post-marketing risk management</td><td colspan="2"></td></tr>
<tr><td colspan="3">(Progress status of review of draft proper use guideline, etc. with related academic societies)</td></tr>
<tr><td>Remarks</td><td colspan="3">(Note: If the product has been selected as a medical device for orphan diseases or a medical device with high medical needs, state so.)</td></tr>
</table>

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(Other considerations)

1 Use the A4-sized form.

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Attached Form 4

Summary of eligibility for In Vitro Diagnostics Conditional Approval System (Type 2)

<table>
<tr><td colspan="2">Name of the applicant</td><td></td></tr>
<tr><td rowspan="2">Name</td><td>Term name*1</td><td></td></tr>
<tr><td>Brand name*2</td><td></td></tr>
<tr><td colspan="2">Intended use or effects</td><td></td></tr>
<tr><td rowspan="2">Requirement A</td><td>Target disease</td><td>☐ It is intended to affect the structure or function of the human body via cauterization or other physical procedures.</td></tr>
<tr><td colspan="2">(General information of target disease, etc.)</td></tr>
<tr><td rowspan="2">Requirement B</td><td>Existing clinical data</td><td>☐ Clinical performance study ☐Clinical research
☐Literature ☐Other</td></tr>
<tr><td colspan="2">(Summary of appropriate clinical data for evaluation with some extrapolation to efficacy and safety for the application range not directly evaluated in existing clinical data)</td></tr>
<tr><td rowspan="2">Requirement C</td><td>Validity of the application according to the target application range</td><td>☐ The physical features of the product to be applied to allow evaluation of its efficacy and safety for the intended use or effect without conducting new clinical trials.</td></tr>
<tr><td colspan="2"></td></tr>
<tr><td rowspan="2">Requirement D</td><td>Post-marketing risk management</td><td></td></tr>
<tr><td colspan="2">(Progress status of review of draft proper use guideline, etc. with related academic societies)</td></tr>
<tr><td>Remarks</td><td colspan="2">(Note: If the product has been selected as IVD for orphan diseases or selected as an IVD with high medical needs, state so.)</td></tr>
</table>

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(Other considerations)

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