

Viktor Frykman/jh
Clinical Trials and Special Permissions
Department

Decision

Date: 2025-05-14

Ref. no.: 5.1.1-2025-033152

Center for Resuscitation Science, Karolinska
Institutet, Department of Clinical Science
and Education, Söder Hospital,
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Concerning application for clinical investigation of medical device

Decision

The Swedish Medical Products Agency has decided that the clinical investigation of the medical device Corpuls3 may start after the validation date on the condition that the Swedish Ethical Review Authority has provided its approval.

CIV-ID:

CIV-25-01-051015

Investigation designation: Double-
D Main Trial

Applicable provisions

Articles 62(4), 70(1) and 70(7)(a) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR)

Presentation of the case

The Center for Resuscitation Science, Karolinska Institutet, Department of Clinical Science and Education, Söder Hospital, (the sponsor) has on 15 April 2025 applied to conduct a clinical investigation of the medical device Corpuls3.

The Swedish Medical Products Agency's assessment was that the application was incomplete. On 25 April 2025, the Swedish Medical Products Agency requested that the sponsor submit additional information no later than 25 May 2025.

The sponsor submitted a response on 8 May 2025.

Grounds

The MDR includes provisions on the conduct of clinical investigations of medical devices, as well as on the structure of applications for authorisation to conduct such investigations.



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According to Article 62(4)(a) of Regulation (EU) 2017/745, a clinical investigation may only be conducted if the clinical investigation has been approved by the Member State in which the clinical investigation is to be conducted, unless otherwise stated. According to Article 70(1) of Regulation (EU) 2017/745, the sponsor shall submit an application and the documentation referred to in Chapter II of Annex XV to that Regulation to the Member State(s) in which the investigation is to be conducted. In Sweden, the application shall be submitted to the Swedish Medical Products Agency, which is the competent authority.

Pursuant to Article 70(7)(a) of Regulation (EU) 2017/745, the sponsor may start the clinical investigation for class I investigational devices or class IIa or IIb non-invasive devices immediately after the validation date of the application provided that a negative opinion has not been issued by the Swedish Ethics Review Authority.

The Swedish Medical Products Agency's assessment is that the application falls within the scope of the provisions on clinical investigations of Regulation (EU) 2017/745 and that it is complete.

The sponsor has indicated in the documentation accompanying the application that the investigational device Corpuls3 is a class IIb non-invasive device. The Swedish Medical Products Agency has no objections to the submitted classification given the manner in which the device is to be used in the clinical investigation.

As the investigational device is a class IIb non-invasive device, Article 70(7)(a) of Regulation (EU) 2017/745 permits the sponsor to start the clinical investigation immediately after the validation date on the condition that the Swedish Ethical Review Authority has provided its approval.

The Swedish Medical Products Agency has decided that the application for the clinical investigation of the medical device Corpuls3 is valid and that the investigation may start after the validation date on the condition that the Swedish Ethical Review Authority has provided its approval.

The validation date is 2025-05-14.

This decision has been taken by head of regulatory group Elin Karlberg following a presentation by regulatory assessor Viktor Frykman.

On behalf of the Swedish Medical Products Agency

Elin Karlberg

Viktor Frykman

This decision has been processed digitally and so is not signed

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