LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY
Victor Frykman
Clinical Trials and Licensing Division

Decision

Date: 21 January Ref. no.: 5.1.2-2025-

Center for Resuscitation Science, Karolinska Institutet, Department of Clinical Science and Education, Södersjukhuset,
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Application for a substantial modification to the clinical trial of a medical device

Decision

The Swedish Medicines Agency grants the application for a substantial modification.

CIV-ID:
CIV-25-01-051015

Designation of the trial:
Double-D Main Trial

Applicable provisions

Articles 71 and 75 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

Chapter 4, Sections 1-2 of the Regulation (2021:631) supplementing EU regulations on medical devices

Description of the case

On 15 December 2025, the Center for Resuscitation Science at Karolinska Institutet's Department of Clinical Science and Education, Södersjukhuset [Stockholm South General Hospital] (sponsor) applied for a substantial modification in the ongoing clinical trial of the Corpuls3 medical device.

The Swedish Medicines Agency has previously assessed the application as complete. The sponsor was notified of this in a confirmation of receipt on 18 December 2025.

In accordance with Chapter 4, Section 2 of the Regulation supplementing EU regulations on medical devices, the Swedish Medicines Agency subsequently sent the application to the Swedish Ethical Review Authority for an opinion.
In the present case, the opinion of the Swedish Ethical Review Authority is constituted by the decision taken by the Authority on 14 January 2026 (see attachment).

The Swedish Medicines Agency's examination of the application for a substantial modification was found to have deficiencies with regard to regulatory aspects. A request for supplementation was therefore sent to the sponsor on 5 January 2026.

In connection with this, the Swedish Medicines Agency announced that the total processing time for the case was extended by 7 days, based on the provisions of Article 75 (4) of Regulation (EU) 2017/745, and that the deadline for the sponsor to submit a response was 11 January 2026 at the latest.
Sponsor's response, with supplementary information, was received on 6 January 2026.

The supplemented application has also been sent to the Swedish Ethical Review Authority for an opinion.

Justification

Regulation (EU) 2017/745 contains provisions regarding the introduction of substantial changes to clinical trials of medical devices, as well as regarding the design of the application to implement such changes.

It follows from Article 75 (1) of Regulation (EU) 2017/745 that, where a sponsor intends to introduce changes to a clinical trial that are likely to materially affect the safety, health or rights of the subjects or the reliability or robustness of the clinical data generated in the trial, the sponsor must, within one week, inform the Member State(s) in which the clinical trial is being conducted or is to be carried out of the reasons for the changes and their nature. The sponsor must include in this notification an updated version of the relevant documentation referred to in Chapter II of Annex XV.

According to Chapter 4, Section 1 of the Regulation, which complements EU regulations on medical devices, it is the Swedish Medicines Agency that examines issues of authorisation to initiate or carry out substantial changes to clinical trials.

Article 75 (3) of Regulation (EU) 2017/745 provides that the sponsor may implement notified material changes in the clinical trial no earlier than 38 days after receipt of a complete application by the Swedish Medicines Agency, provided that the Agency has not informed the sponsor that the application has been rejected on the grounds set out in Article
71.4 or for reasons of public health, the safety or health of subjects and users, or public policy, and provided that a negative opinion regarding the substantial modification of the clinical trial has not been issued by the Swedish Ethical Review Authority. Pursuant to Article 75 (4), the Agency may extend the 38-day processing period by a further 7 days in order to consult experts.

Pursuant to Chapter 4, Section 2 of the Regulation with supplementary provisions to the EU regulations on medical devices, the Swedish Medicines Agency has sent the application to the Ethical Review Authority for an opinion.
The Swedish Ethical Review Authority has not issued a negative opinion. The

Swedish Medicines Agency grants the application for a substantial

modification.

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This decision has been taken by Group Manager Elin Karlberg, following a presentation by Regulatory Investigator Viktor Frykman.

On behalf of the Swedish Medicines Agency

Elin Karlberg Viktor Frykman

This decision has been digitally managed and is therefore unsigned

Attachment: The Ethical Review Authority's opinion decision, dated 14 January 2026