EUROPEAN COMMISSION

Expert decision and opinion in the context of the Clinical Evaluation Consultation Procedure (CECP)

Expert panels on medical devices and in vitro diagnostic devices (Expamed)

Contents

Scope of this expert decision

This decision reflects the views of independent experts (MDR Article 106) on the relevance to produce an opinion on the clinical evaluation assessment report (CEAR) of the notified body for this device. The expert decision is provided in the context of the clinical evaluation consultation procedure (CECP), which is an additional element of conformity assessment by notified bodies for specific high-risk devices (MDR Article 54 and Annex IX, Section 5.1).

Scope of this expert opinion

This scientific opinion reflects the views of independent experts (MDR Article 106) on the clinical evaluation assessment report (CEAR) of the notified body. The advice is provided in the context of the clinical evaluation consultation procedure (CECP), which is an additional element of conformity assessment by notified bodies for specific high-risk devices (MDR Article 54 and Annex IX, Section 5.1).

The notified body is obliged to give due consideration to views expressed in the scientific opinion of the expert panel and in particular in case experts find the level of clinical evidence not sufficient or have serious concerns about the benefit-risk determination, the consistency of the clinical evidence with the intended purpose including the medical indication(s) or with the post-market clinical follow-up (PMCF) plan.

Having considered the expert views, the notified body must, if necessary, advise the manufacturer on possible actions, such as specific restrictions of the intended purpose, limitations on the duration of the certificate validity, specific post-market follow-up (PMCF) studies, adaption of instructions for use or the summary of safety and clinical performance (SSCP) or may impose other restrictions in its conformity assessment report.

In accordance with MDR Annex IX, 5.1.g., the notify body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report.

1 ADMINISTRATIVE INFORMATION

Date of start of procedure	14/04/2026
Notified Body number	NB 0344
Internal CECP dossier #	EMA/EX/0000340980
Medical device type	Q0101 retinal stimulation systems
Intended purpose	Restoration of limited visual perception in severely sight impaired persons with functional optical nerve and retinal ganglion cell layer who have lost their central vision due to the degeneration of photoreceptor cells caused by atrophic dry age-related macular degeneration (AMD).
Risk class / type	Class III
Screening step: medical field / competence area	Ophthalmology

2 – DECISION OF SCREENING EXPERTS: NOTIFICATION OF NB AND COMMISSION REGARDING THE INTENTION TO PROVIDE AN OPINION

2.1 Decision of the screening experts

Table covers all three criteria, intended to support their consistent and conscientious application

Date of decision	20/04/2026
Screening panel decision	
Is there intention to provide a scientific opinion?	☒ **Yes** ☐ **No** ☐ **Insufficient information to reach a conclusion**
In case the information was found insufficient to reach a conclusion: summary of reasons (see MDR Annex IX Section 5.1 point c)	
BRIEF TEXT (indicatively max. 150 words)	
Summary as to why there is intention to provide an opinion	
This is a set of medical devices including a wireless subretinal implant and delivery system, glasses equipped with an image capture and projection module, a pocket processor, a stand-alone software accessory for patient training, a range of fitting accessories for the glasses, and a rehabilitation accessory kit. The device is considered novel, as acknowledged by both the manufacturer and the Notified Body, although based on previously existing technology. The principal innovation is the use of an active, wireless subretinal powered by an external Near-Infrared (NIR) light, which is converted by a photovoltaic array into electric stimulation of the inner retinal neurons. This approach eliminates the need for wired power delivery and enables subretinal stimulation in the area of central retinal atrophy. In addition, the device incorporates a comparatively higher spatial resolution (300 pixels) than earlier retinal prostheses contributing to improved visual discrimination compared to other retinal implant devices. Its novelty resides in the optimised integration of photovoltaic subretinal stimulation with modern image projection and processing, specifically designed to address central vision loss due to atrophic dry AMD, a population for which no restorative therapies previously existed.	

Clinical evidence remains limited, consisting primarily of a small number of early feasibility and clinical investigations with restricted sample sizes and incomplete long-term reporting. In addition, serious adverse events related to the implantation procedure have been reported. Given the novel indication, invasive nature of the device, limited clinical dataset, and residual safety uncertainties, an expert panel opinion is warranted.

Summary as to why there is *no* intention to provide an opinion

N/A

Any other comments

N/A

2.2 Assessment of the three screening criteria

Criterion 1: Novelty of device under assessment and possible clinical / health impact

1.1 Overall degree of novelty

☐ No novelty: Neither device nor clinical procedure is novel
☐ Low level of novelty

☐ Medium level of novelty

☒ High level of novelty

Short description of the novelty, including main dimension(s) of novelty

The device uses a photovoltaic subretinal implant powered by externally delivered near-infrared light, eliminating wired power connections or implanted electronics packages. Power and data are transmitted optically rather than electrically.

Unlike earlier retinal prostheses developed mainly for retinitis pigmentosa, this system is specifically designed to replace lost photoreceptor function in the central retina of patients with atrophic dry age-related macular degeneration, a population previously lacking any restorative treatment.

The combination of subretinal stimulation at the level of bipolar cells, higher pixel density than previous devices, and image capture, processing, and projection via external glasses enables usable central form vision (e.g. letter and word recognition), rather than mere light perception.

1.2 Possible negative clinical / health impact resulting from novelty

Estimated* possible clinical and/or health impact related to the novel aspects of the device

* This can entail uncertainty. Not only *known* clinical / health impacts but also *possible* ones (conceivable uncertainties, hazards, risks) should be taken into account but need to be supported by a scientific, clinical or technical reasoning.
☐ No clinical or health impact ☐ Minor clinical or health impact ☐ Moderate clinical or health impact ☒ Major clinical or health impact
Possible major clinical or health impact related to the novel aspects of the device
The potential health impact is substantial, as this is the first implantable device to demonstrate restoration of usable central form vision in a patient population for which no restorative treatments previously existed.

Criterion 2: Scientifically valid health concerns leading to significantly adverse changes in the benefit-risk profile of a specific group / category of devices and relating to **a) Component(s)** **b) Source material(s)** **c) Impact on health in case of failure of the device**	
2.1 Information received from Secretariat:	☐ Yes ☒ No
2.2 Other information available to experts:	☐ Yes ☒ No

Criterion 3: Significant increase of serious incidents of a specific group / category of devices relevant for the device under assessment ***(if information is available, it will always be provided by the expert panel secretariat)***	
3.1 Information received from secretariat?	☐ Yes ☒ No

2.3 Indication of appropriate thematic panel in case opinion is required

Indication of appropriate thematic panel and competence area		
	Expert panels	Medical and scientific/technical competence areas (these may correspond to sub-groups)

☐	**Orthopaedics, traumatology, rehabilitation, rheumatology**	☐ 1. Joint replacements (hip, knee, shoulder) ☐ 2. Spinal devices ☐ 3. Non-articulating devices, rehabilitation
☐	**Circulatory system**	☐ 1. Prosthetic heart valves and devices for heart valve repair ☐ 2. Cardiovascular stents (metallic and bio-resorbable) and vascular prostheses ☐ 3. Active implantable cardiac devices and electrophysiological devices ☐ 4. Structural interventions and new devices (e.g. LAA/PFO occluders, heart failure devices) ☐ 5. Cardiac surgery including extracorporeal membrane oxygenation, cardiopulmonary bypass devices, artificial hearts and left ventricular assist devices
☐	**Neurology**	☐ 1. Central and peripheral nervous system devices ☐ 2. Implants for hearing and vision (sensory recovery) ☐ 3. Neurosurgical devices
☐	**Respiratory, anaesthesiology, intensive care**	☐ Respiratory and anaesthetic devices
☐	**Endocrinology and diabetes**	☐ Endocrinology and diabetes devices
☐	**General and plastic surgery Dentistry**	☐ 1. Surgical implants and general surgery ☐ 2. Plastic surgery and wound care ☐ 3. Maxillofacial surgery & Devices for dentistry e.g. oral surgery, implantology, dental materials etc.
☐	**Obstetrics and gynaecology including reproductive medicine**	☐ Devices for obstetrics and gynaecology
☐	**Gastroenterology and hepatology**	☐ Devices for gastroenterology and hepatology
☐	**Nephrology and urology**	☐ Devices for nephrology and urology
☒	**Ophthalmology**	☒ Devices for ophthalmology

3 – SCIENTIFIC OPINION OF THE THEMATIC EXPERT PANEL/SUB-GROUP

3.1 Information on panel and sub-group

Date of opinion	12/06/2026
Expert panel name	Ophthalmology
Sub-group of expert panel (where relevant)	N/A

3.2 Detailed aspects of the opinion as required by MDR Annex IX Section 5.1

Opinion of the expert panel on the specific aspects of the clinical evaluation assessment report of the notified body (CEAR)[1]
1. Overall opinion on the NB's assessment of the manufacturer's clinical evaluation report
The NB's assessment is based on two first-in-human/ feasibility investigations with a very limited number of patients and an ongoing multi-centre, prospective, single-arm pivotal investigation (the PRIMAvera study) with 38 patients enrolled. The primary endpoints for the pivotal investigation are the proportion of subjects with an improvement of visual acuity of logMAR 0.2 or more from baseline to 12 months, and the number and severity of device- and procedure-related serious adverse events (SAEs) at 12 months. The planned follow-up period in the pivotal investigation is 36 months, with an optional study extension that extends the follow-up to 72 months. The NB's assessment is based on 12 months of follow-up. The results from the clinical investigations show an improvement in visual acuity for study patients, and demonstrate that the safety endpoints were met. The NB's CEAR is deemed adequate since it reflects and discusses the CER and the CEP in a comprehensive way. The NB's assessment of the safety, security, and performance aspects of the medical device based on the outcome of the three clinical investigations is deemed adequate. However, in the opinion of the experts, several aspects of relevance for the assessment were not sufficiently documented in the CEAR. They were however addressed by the NB in response to questions from the experts, and the responses were found satisfactory. These aspects include the total duration of the follow-up in the pivotal study and its justification based on the lifetime of the device; the impact of the environment on the implant, including other technical equipment and applications as well as sunlight; and Software of Unknown Provenance (SOUP) incidents. The experts have a remaining concern regarding the fact that migraine is not considered a contraindication for the device and assess the NB's answer to this question as unsatisfactory.

[1] According to Annex IX Section 5.1 of Regulation (EU) 2017/745 - Assessment procedure for certain class III and class IIb devices.

Patients with migraine can have a hypersensitivity to flickering light. It is recommended to consider possible effects of the flickering light stimulation by the PRIMA device in patients with migraine, and to consider a contraindication for relevant migraine patients (to be precisely defined, e.g. in terms of frequency and intensity of the migraines).

2. Opinion on the NB's assessment of the adequacy of the manufacturer's benefit-risk determination

The NB's assessment of the benefit-risk determination of the device based on the outcomes of the pivotal study is deemed adequate given the practical limitations in sample size, inclusion and exclusion criteria, and longitudinal design. The objectives and endpoints of the clinical evaluation are deemed adequate. The NB satisfactorily answered the open questions about inclusion criteria, endpoint testing, operational lifetimes and aspects of explantation. The overall design of the study and the results obtained from it can be agreed by the panel and are in line with what is expected from the SOTA. It is recommended to reconsider contraindications with regard to patients with migraine, as mentioned in Section 1.

The benefit-risk determination for technical and environmental light and other interferences with the PRIMA components is deemed adequate, following the satisfactory NB's answer to the related open questions. As mentioned in Section 1, these aspects could have been addressed in the CEAR.

However, the experts have remaining concerns about the benefit-risk of the device in real life. More specifically, the experts note that the daily use of the device is quite limited as it is estimated to remain in the 1-2 hour range. This needs to be balanced against the invasive nature of the procedure and the extensive training and rehabilitation programme for the patient. The experts strongly recommend for the estimated daily use, type of activities for which the device is used, and the available alternatives, including text-to-speech systems, to be clearly outlined in the documentation intended for healthcare professionals and patients, to support a robust case-by-case benefit-risk decision for each patient.

3. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the intended purpose, including medical indication(s)

The experts agree with the NB's assessment that the manufacturer's clinical evidence is overall consistent with the intended purpose/ medical indications, i.e. the treatment of central vision loss due to advanced atrophic AMD (geographic atrophy) involving the fovea.

However, the experts are of the opinion that an upper age limit should be implemented, unless it can be sufficiently demonstrated expected that the benefits of the procedure will outweigh the risks in older patients, taking into account the benefit-risk considerations in Section 2.

The experts also emphasise that the additional elements provided by the NB in responses to the experts' questions, such as the necessary cognitive/ mental abilities of the patients and their level of education/ compliance/ motivation which will be essential factors for the training and rehabilitation programme, are critical parameters to make a decision on the implantation. The experts believe that these aspects were not sufficiently addressed in the CEAR, and recommend for the medical indications, particularly the item "Understands the constraints of the necessary rehabilitation", to be refined/ further detailed accordingly in the clinical documentation and in the documentation intended for patients and healthcare professionals.

4. Opinion on the NB's assessment of the consistency of the manufacturer's clinical evidence with the PMCF plan

The experts have the following comments on the NB's assessment of the consistency of the manufacturer's clinical evidence with the PMCF plan.

First, the experts believe that the choice of primary safety outcome in the PMCF study, "Natural visual acuity loss after PRIMA implantation measured without the PRIMA Companion Glasses at 12 months after implantation compared to baseline", is not sufficiently justified based on the clinical data gathered so far. The experts recommend reviewing the justification for this primary safety outcome and considering whether another primary safety outcome, such as procedure- and device-related adverse events, would be more adequate.

Second, and in line with Sections 2 and 3, the experts recommend more thoroughly defining in the PMCF study both the patient population and the expected daily use and type of activities for which the device is used, to ensure an adequate benefit-risk decision for each patient implanted and entering the PMCF study.

Finally, the experts recommend collecting data on the types of medical centres (e.g. public hospitals, private practices, etc.) in which the device will be implanted, in order to gather information on the real-world patient population that will have access to the device. The experts also recommend considering the need for a certification process for the medical centres that will perform the PRIMA implantation, in order to ensure appropriate training, available equipment, and consistency of the medical decision and of the procedure, as was implemented in some Member states for other novel ophthalmologic products.

Apart from these elements, the PMCF study as planned by the manufacturer and assessed by the NB is deemed adequate since it includes both active and passive post-market surveillance data obtained with an adequate and comprehensive methodology to monitor safety, security, and performance of the PRIMA components in the market.

3.3 Summary of expert panel opinion

PRIMA Products is a novel set of medical devices intended for restoration of limited visual perception in severely sight impaired persons with functional optical nerve and retinal ganglion cell layer who have lost their central vision due to the degeneration of photoreceptor cells caused by atrophic dry AMD. The set includes a wireless subretinal implant and delivery system, glasses equipped with an image capture and projection module, a pocket processor, a stand-alone software accessory for patient training, a range of fitting accessories for the glasses, and a rehabilitation accessory kit.

The PRIMA implant is a 2×2mm wide and 30µm thick crystalline silicon array comprising 378 photovoltaic pixels, each 100µm in size. It is implanted subretinally within the atrophic lesion. A frame-mounted camera on the PRIMA glasses captures images, and projects them, after processing onto the implant, using near-infrared (880nm) light. The implant's pixels convert near-infrared light into electric pulses to stimulate retinal bipolar cells, restoring the flow of visual information.

The NB's assessment of the manufacturer's clinical evaluation report is based on two first-in-human/ feasibility investigations and an ongoing multi-centre, prospective, single-arm pivotal investigation (the PRIMAvera study). The NB's assessment of the safety, security, and performance aspects of the medical device based on the outcome of the three clinical investigations is deemed

adequate. However, in the opinion of the experts, several aspects of relevance for the assessment were not sufficiently documented in the CEAR. These aspects include the total duration of the follow-up in the pivotal study and its justification based on the lifetime of the device; the impact of the environment on the implant, including other technical equipment and applications as well as sunlight; and SOUP incidents. They were however addressed by the NB in response to questions from the experts, and the responses were found satisfactory. The experts have a remaining concern regarding the fact that migraine is not considered a contraindication for the device.

The NB's assessment of the benefit-risk determination is deemed adequate. However, in the opinion of the experts, several aspects of relevance for the benefit-risk determination of this novel device were not sufficiently documented in the CEAR, such as the technical and environmental light and other interferences with the PRIMA components. They were however addressed by the NB in response to questions from the experts, and the responses were found satisfactory. In addition, the experts have remaining concerns about the benefit-risk of the device in real life. More specifically, the experts note that the daily use of the device is quite limited as it is estimated to remain in the 1-2 hour range. This needs to be balanced against the invasive nature of the procedure and the extensive training and rehabilitation programme for the patient. Recommendations are outlined in the section below.

The experts agree with the NB's assessment that the manufacturer's clinical evidence is overall consistent with the intended purpose/ medical indications, i.e. the treatment of central vision loss due to advanced atrophic AMD (geographic atrophy) involving the fovea. However, in the opinion of the experts, several aspects of relevance for the implantation decision impacting the intended patient population were not sufficiently documented in the CEAR. They were however addressed by the NB in response to questions from the experts, and the responses were found satisfactory. Recommendations are outlined in the section below.

The experts agree that the NB's assessment of the clinical evidence is overall consistent with the PMCF plan, which includes both active and passive post-market surveillance data obtained with an adequate and comprehensive methodology.

The experts have specific comments/ recommendations for the PMCF study, which are outlined in the section below.

3.4 Recommendations

The experts recommend the following:

- Including migraine as a contra-indication, precisely defining the type of migraines concerned, e.g. in terms of frequency and intensity.
- Clearly outlining the estimated daily use, type of activities for which the device is used, and the available alternatives, including text-to-speech systems, in the documentation intended for healthcare professionals and patients.
- Considering an upper age limit for the patient population, unless it can be sufficiently demonstrated expected that the benefits of the procedure will outweigh the risks in older patients, taking into account the benefit-risk considerations already mentioned.
- Refining/ further detailing the medical indications, particularly the item "Understands the constraints of the necessary rehabilitation", in the appropriate documentation, taking into account the necessary cognitive/ mental abilities of the patients and their level of education/ compliance/ motivation.

The experts also recommend the following for the PMCF study:

- Reviewing the justification for the primary safety outcome and considering whether another primary safety outcome, such as procedure- and device-related adverse events, would be more adequate.
- More thoroughly defining both the patient population and the expected daily use and type of activities for which the device is used.
- Collecting data on the types of medical centres in which the device will be implanted.
- Considering the need for a certification process for the medical centres that will perform the PRIMA implantation, in order to ensure appropriate training, available equipment, and consistency of the medical decision and of the procedure, as was implemented in some Member states for other novel ophthalmologic products.

3.5 Stakeholder information, where available

Relevant information provided by stakeholders, if applicable[2]
Has the Secretariat provided information from stakeholders?
☐ Yes ☒ No
Summary of the information that was taken into account and how it was taken into account.
N/A

3.6 Divergent positions in case no consensus was reached

Please indicate how many of the experts of the panel or sub-group had divergent views
N/A
Summary of divergent positions
N/A

[2] According to Article 106.4 of Regulation (EU) 2017/745, expert panels shall take into account relevant information provided by stakeholders including patients' organisations and healthcare professionals when preparing their scientific opinions.