**Appraisal Plan**

For

[Device Name]

## Ranking from MDCG 2020-6 (April 2020)

Table 1: MDCG 2020-6 rank

| **Rank** | **Types of clinical data and evidence** |
| --- | --- |
| 1 | Results of high-quality clinical investigations covering all device variants, indications, patient populations, duration of treatment effect, etc |
| 2 | Results of high-quality clinical investigations with some gaps |
| 3 | Outcomes from high-quality clinical data collection systems such as registries |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified, and acceptability justified |
| 5 | Equivalence data (reliable / quantifiable) |
| 6 | Evaluation of state of the art, including evaluation of clinical data from similar devices |
| 7 | Complaints and vigilance data; curated data |
| 8 | Proactive PMS data, such as that derived from surveys |
| 9 | Individual case reports on the subject device |
| 10 | Compliance to non-clinical elements of common specifications considered relevant to device safety and performance |
| 11 | Simulated use / animal / cadaveric testing involving healthcare professionals or other end users |
| 12 | Pre-clinical and bench testing / compliance to standards |

## Suitability

Table 2: Criteria of suitability[[1]](#footnote-1)

| **Suitability criteria** | **Description** | **Grading System** | |
| --- | --- | --- | --- |
| Appropriate device | Were the data generated from the device in question? | D1 | Subject device |
| D2 | Equivalent device / similar devices |
| D3 | Similar device / alternative treatments |
| Appropriate device application | Was the device used for the same intended use (e.g., methods of deployment, application, etc.)? | A1 | Same use |
| A2 | Off-label use |
| A3 | Unspecified use |
| Appropriate patient group | Were the data generated from a patient group that is representative of the intended treatment population (e.g., age, sex, etc.) and clinical condition (i.e., disease, including state and severity)? | P1 | Targeted population |
| P2 | Contraindicated population |
| P3 | Other population |
| Acceptable report/data collation | Do the reports or collations of data contain sufficient information to be able to undertake a rational and objective assessment? | R1 | Key safety and performance measures |
| R2 | Other safety and performance measures |
| R3 | No safety and performance measure |

## Contribution

Table 3: Criteria of contribution[[2]](#footnote-2)

| **Data contribution criteria** | **Description** | **Grading System** | |
| --- | --- | --- | --- |
| Data source type | Was the design of the study appropriate? | T1 | Yes |
| T2 | No |
| Outcome measures | Do the outcome measures reported reflect the intended performance of the medical device? | O1 | Yes |
| O2 | No |
| Follow up | Is the duration of follow-up long enough to assess whether duration of treatment effects and identify complications? | F1 | Yes |
| F2 | No |
| Statistical significance | Has a statistical analysis of the data been provided and is it appropriate? | S1 | Yes |
| S2 | No |
| Clinical significance | Was the magnitude of the treatment effect observed clinically significant? | C1 | Yes |
| C2 | No |

## Oxford Level of evidence (LoE)

Table 4: Level of clinical evidence[[3]](#footnote-3) for therapy or prevention of disease

| **LoE** | **Description** |
| --- | --- |
| 1 | Systematic reviews of randomized controlled trials  Individual randomized controlled trials |
| 2 | Systematic reviews of cohort studies  Individual cohort study  low quality randomized controlled trials |
| 3 | Systematic review of case-control studies  individual case-control study |
| 4 | Case series |
| 5 | Expert opinion |

## Application of appraisal methods

Table 5: Application of appraisal criteria by type of clinical data

| **Appraisal criteria**  **Type of clinical data** | **MDCG 2020-6** | **Suitability** | **Contribution** | **LoE** |
| --- | --- | --- | --- | --- |
| Clinical/PMCF investigation / PMCF registry | Yes | Yes | Yes | Yes |
| PMCF survey | Yes | - | - | - |
| Literature article for the subject device / equivalent device | Yes | Yes | Yes | Yes |
| Literature article for SoA | Yes | - | - | - |
| Literature article for AC | Yes | Yes | Yes | Yes |
| PMS data hold by the manufacturer for subject device / equivalent device | Yes | - | - | - |
| External vigilance/recall data | Yes | - | - | - |
| Preclinical data | Yes | - | - | - |

1. Criteria derived from the appraisal criteria defined in IMDRF MDCE WG/N56FINAL:2019 [↑](#footnote-ref-1)
2. Criteria derived from the appraisal criteria defined in IMDRF MDCE WG/N56FINAL:2019 [↑](#footnote-ref-2)
3. Criteria derived from [Oxford Centre for Evidence-Based Medicine: Levels of Evidence (March 2009)](https://www.cebm.ox.ac.uk/resources/levels-of-evidence/oxford-centre-for-evidence-based-medicine-levels-of-evidence-march-2009) for Therapy / Prevention / Aetiology / Harm [↑](#footnote-ref-3)