Health Technology Review	
Technology Ref.:	HTA23072
Technology Name/Version/Model:	Omnigene Oral OME-505.005+ACP119 (Ziwig Endotest)
Approvals by International Bodies:	**CE Mark**
Company name:	**Aurora Drug Store L.L.C**
Agent in UAE:	Ann Lydia Gomez
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Short Description of the Technology:	Ziwig Endotest®, innovative and non-invasive, diagnostic tool that allows the early detection of endometriosis with a performance that exceeds that of conventional diagnostic tests: sensitivity >95%, specificity >95%, diagnostic accuracy (AUC) of >95%. Ziwig Endotest® is Based on analysis of salivary miRNA via 2 cutting-edge technologies: NGS (Next Generation Sequencing) and Artificial Intelligence (AI). (109 different microRNAs are involved in the pathophysiological mechanisms of endometriosis). It is a prescriptive-use only device**, intended for patients between the age of 18 and 43 years with symptoms suggestive of endometriosis.** Saliva collection must be done under the supervision of a healthcare professional**.** Ziwig Endotest is the result of the synthesis of 4 world-class innovations in endometriosis: • The use of a non-invasive saliva sample. • The use of all human miRNAs as novel biomarkers. • The use of next-generation, reliable, accurate and reproducible sequencing. The use of Ziwig's diagnostic engine to meet the challenge of high-volume data

Health Technology Assessment Team Recommendation:	Approve

Summary of Review:

Ziwig Endotest® in vitro diagnostic device reserved exclusively for professional use for the diagnosis of endometriosis on salivary samples. Ziwig Endotest® is an innovative diagnostic method based on the analysis of salivary miRNAs and the identification of phenotypic profiles characteristic of endometriosis identified by NGS (Next Generation Sequencing) method and modelled by AI.

Advantages	Disadvantages
CE Marked	For professional use only
The test help in diagnosing endometriosis at using a simple saliva sample.	Lack of cost effectiveness study
It is a simple saliva test that is far more accurate (based on the current available data) with a much higher sensitivity and specificity compared to the current non-invasive methods of diagnosis – history, examination, USS, MRI, biomarkers.	Saliva Test may not provide as detailed and comprehensive information about the extent or severity of the disease compared to the standard method
Non- Invasive Test	Limited ability of saliva test to detect certain aspects of endometriosis
Ziwig Endotest® has a sensitivity >95%, specificity >95%, diagnostic accuracy (AUC) of >95%.	

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. Approval on Endoset version OME-505.005+ACP119 for the use on symptomatic women between the ages of 18-43.
2. Information Security conditionally approved as following.
    - Patient Health Information to be anonymised.
    - VIP and Royal data to be excluded.
    - The requestor to identify solutions within UAE and compliant with applicable Legal and Regulatory requirements.
    - Right to audit by regulatory body (DOH)
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
4. Provision of regular updates and reports about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image

Population, setting and intended user for Technology "Ziwig Endotest"

- **Population/ Intended User**.
  - A non-invasive diagnostic tool that allows for the early detection of endometriosis
- **To be performed by**:
  - By Healthcare Professional only
- **Clinical Setting:**
  - Hospitals, clinic, etc.
- **Condition of use:**
  - As per Manufacturer instruction
- **Exclusion criteria:**
  - Other conflicting medical issues