Application reference no.	MM/2023/Dec/21
Applicant Name	Abanis Nayak
Innovators Name	Abanis Nayak
Company/Institute Name	ZTOP IOT SOLUTIONS PRIVATE LIMITED
Email Id	ZTOPIOTSOLUTIONS@GMAIL.COM
Applicant Type	Startup
Contact Number	9938115906
MedTech Type	Medical Device
Intended Use Statement	TAI Apparatus (Toical Analgesic Inducer). Around 2 in 3 children and 1 in 4 adults have some sort of fear or phobia against prick of a needle. Medical Study also suggests that around 16% avoid taking vaccination for fear of needles. We are developing a stand-alone TAI apparatus, a electronic stub whose main function is to drastically reduce the pain from the prick of a Needle. It has a lot of emotional value and also a good Diplomatic Product to give while giving vaccines to other countries by our Government. A Made in India product for the World.
Target Population	Anyone who takes an injection or a blood draw.
Proposed Manufacturing Process Flow	After Manufacturing license, we will finalise the Process flow. A lot depends on costing.
Risk Classification of Medical Device / IVDs	Class B
Summary of The Technology	We are using cryotech to get and maintain the stub at a particular temperature. At the point of prick prior to the prick the stub will be placed for around 5-6 seconds during which time a vibration will also be given and after that the prick can be done. The main challenge is the control system, fast sensors, heat radiation tech and speical adhesives.
Financial Opportunities	INTENT
Name of the Technology	TAI Apparatus
Use Environment	Hospital_Clinic
Design Information	We have done the Prototype, lab testing. Currently we are designing a MVP and then go for Clinical Trials.
Area of Application	Where ever a needle will be pricked, the device can be used. It is a standalone and independent device.
Type of Medical device/diagnostic	Medical device or IVD having available predicate device or diagnostic
Stage of your Innovation	Bench Testing of Prototypes for Manufacturing Test License
Type of Support(Handholding) needed	Regulatory Strategy
Query	We are looking for guidance as to how to take the device from design to the market. Currently we are working on building the MVP. Also we are looking for fund support.

Additional Information sought from innovator (as applicable)

1. Image of your device/diagnostic kit (with labels):

2. Information on current practice/standard of care/Predicate device:
   Currently when given an injection or blood draw, nothing is done to reduce the pain from the prick of the needle. We have developed this standalone electronic device which will help drastically reduce the pain from the prick of a needle.

   Trypanophobia is fear of needles, study suggests that around 16% of adults do not take vaccination due to some fear of needles. Also the fear can impact ones life.

3. Principle of operation:

We are using cryogenic principle to maintain the temperature of the stub to a particular temperature. The stub needs to be placed a the point of the prick prior to the prick for 5-6 seconds, when the stub is placed we also give a vibration to make it more effective. After the stub is removed, we have 10-15 seconds to inject. The process will drastically reduce the pain from the prick of a needle.

4. Information on accessories (if any):
   No accessories needs per se.
5. Material of construction:
   We most probably will be using composite or healthgrade polymer, we are still doing the MVP and we are working it out.
6. Dimensions of the product:
   Current dimension is 20*26*30 cm but might change.
7. Data generated so far indicating substantial equivalence of proposed technology to predicate device (safety & efficacy)/ diagnostic (sensitivity & specificity):

   We are waiting for Clinical Trails for data.

8. Test license from CDSCO obtained: **Yes/No**
   Not yet
9. Provide details of references/publications made during technology development/patents filed:
   Patent has been filed for the product. Publication will be done as we go for trails.
10. USP/Value proposition of your technology:
    We have an emotional disruptive product – any person or atleast most would want to have a pain-less injection.
    This can also help the Government, just imagine we are supplying Vaccines to different countries, with that if we also give them a device which will drastically reduce the pain from the prick of a needle – it will be a great thing.