FDA Unique Device Identification Exception or Alternative Request

In the narrative section below, please provide your answers to the following questions:

1. What device or devices would be subject to the exception or alternative?

2. Which provisions of 21 CFR 801 Subpart B are you requesting an exception from or an alternative to?

3. If you are requesting an exception, explain why you believe the requirements that you are requesting an exception from are technologically infeasible.

4. If you are requesting an alternative, describe the alternative and

    a. Explain why it would provide for more accurate, more rapid, or more precise device identification than the requirements of 21 CFR 801 Subpart B or

    b. Explain how the alternative would better ensure the safety or effectiveness of the devices that would be subject to the alternative.

5. What is the number of labelers that would be affected if we granted the requested exception or alternative? (Provide, if known)

6. What is the number of devices that would be affected if we granted the requested exception or alternative? (Provide, if known)

Narrative Section:

Narrative Section (continued):