


March 12, 2013

MEMORANDUM TO: SSD Case File # 13-06
Morpho Detection, Inc.

Amended Sealed Source and Device Registration
NR-0399-D-101-E

FROM: Ujagar S. Bhachu 
Licensing Branch, FSME/MSSA

SUBJECT: No Checklist or Safety Evaluation Performed

Morpho Detection, Inc. by a letter dated November 1, 2012, requested the amendment of the referenced certificate to reflect a change in naming convention of Model I3 (Itemiser 3) as I3E (Itemiser 3 Enhanced). Morpho Detection, Inc. stated that I3E is technologically, mechanically, functionally and radiologically the exact same device as its previous version I3, however, I3e has upgraded software and a USB instead of a floppy drive. After reviewing the request and the information provided by Morpho Detection no safety evaluation or the preparation of a checklist for the sealed source device was found necessary.