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MEMORANDUM

TO: Docket No. 00D-0053
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane (HFA-305), Room 1061
Rockville, MD 20852

FROM: Paragon Reprocessing Services, Inc.
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Little Rock, AR 72211

SUBJECT: Comments on Proposed FDA Guidelines for Reprocessing and Reuse of Single-Use Devices

DATE: April 10, 2000

Per the agency's request, the following four pages contain Paragon Reprocessing Services, Inc.'s comments/questions on the proposed FDA Guidelines for Reprocessing and Reuse of Single-Use Devices:

1. Pulse Oximeters (Finger Sensors) are currently being reprocessed by third party and hospital reprocessors.
2. Will the recognized consensus performance standards or performance tests recommended by the OEMs be available to reprocessors?
3. If a reprocessor is registered as a remanufacturer, will that reprocessor be allowed to remarket devices for sale in other countries?
4. If OEMs are allowed to print warning statements on the use instructions with a device, what will the agency do to insure that those warnings are legitimate?
5. The RPS should take into consideration historical clinical studies with regard to infection rates comparing EP Catheter reuse with EP Catheter single use. The significant clinical data demonstrating the low infection risk of these devices should re-categorize EP Catheters as moderate risk requiring a 510(k), not PMA

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6. Pre-market Regulatory Requirement - The objective of setting enforcement priorities, as described in the "Risk Scheme Guidance," is to establish the degree of risk posed by reprocessing of devices labeled for single use. Furthermore, risk categories would serve as the basis for enforcement of pre-market regulatory requirements, both pre-market approval (PMA) and pre-market notification 510(k) are being considered. Reprocessed devices should not require an approved PMA application before marketing. All devices for reprocessing are pre-approved devices. Reprocessing a device does not change the intended use of the device. Reprocessing of devices labeled for single use does change the labeling information, however, going from single use to multiple use. A 510(k) submission would show substantial equivalence of a reprocessed device to a single-use device. Stability studies would support the label claim for multiple use to show the device remains safe and effective.
7. Evaluating the Risks - Within this section of the document, Question #4 (Infection) reads, "Does a reusable device exist that has an equivalent design and the same intended use as the SUD?" The document explains that the OEM provides the user with reprocessing instructions. Question #4, posed as an evaluation question, and discussion of OEM reusable devices supports the practice of reuse. Reprocessing of devices by third parties enforces safe cleaning and sterilization practices. A "No" answer to Question #4 should not be a consideration for high risk.

Question #3 (Infection) points to features that could prevent adequate cleaning and sterilization. A "Yes" answer should not be an automatic consideration for high risk. Scientific validation methods have been developed to adequately clean and sterilize a device with complex design features.

Both sections of risk evaluation, Risk of Infection and Risk of Inadequate Performance, contain questions which reference the existence of postmarket information to suggest increased risk. Within the scope of published data, evidence supporting and opposing reuse can be sited including studies and test results to support both views. Only proven, scientific data or formal FDA reports should be considered for evaluation. In addition, all questions requiring subjective responses should be withdrawn as part of the evaluation process.

Devices not on the list of frequently reprocessed SUD's should not be automatically considered to be high risk. Each new device type should be subject to the final categorization scheme assigning an appropriate risk category.

8. The agency's regulatory enforcement strategy for SUD's as defined in the February 8, 2000 draft document, should adopt the same requirements and time lines found in the Medical Device Amendments of 1976.

The Medical Device Amendments of 1976 allowed for the marketing of medical devices, which were initially manufactured prior to the act, to remain in the market place without the requirement for pre market submissions. Paragon would request the same consideration for reprocessors. The reprocessed devices which a firm has listed with the agency, as part of their listing requirements be given the same legal consideration as pre amendment devices.

The Medical Device Amendments of 1976 allowed a period of thirty months for manufacturers to file PMA submissions on those devices marketed prior to May 1976 that were later classified as Class III devices. The agency has indicated in the draft guidance document that a reprocessor will be required to submit a PMA within six months of the final issuance of the guidance document. This time line for PMA submission should be increased to 30 months to reflect the precedence set by the Medical Device Amendments of 1976.

9. A fundamental element of the draft guidance "Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," published February 8, 2000, calls for reprocessor submissions to be based on the classification status of the reprocessed device. That is, a reprocessed Class III device would require a PMA application and a reprocessed Class II device would require a 510(k) premarket notification. It also appears that a now exempt Class II or Class I device that is found to have a moderate or high risk would also require a 510(k) premarket notification.

This approach is inappropriate in that the PMA process was designed for a completely different purpose, that is to show safety and efficiency for a new or modified Class III device.

Therefore, the PMA process should not be used as the submission form for a reprocessed Class III device. A PMA application has several sections which have no applicability to a reprocessed SUD. These include:

- ❖ Indications for Use. The IFU information has already been approved in the original PMA. For such Class III devices, the hospital for whom the devices are being reprocessed should keep a copy of the IFU, thereby relieving the reprocessor of the requirement to supply IFU information.
- ❖ Clinical Investigations. This information is unnecessary since the Class III device has already been proven effective in the original PMA and safety can be demonstrated by reprocessing using QSR compliant manufacturing operations.
- ❖ Non-Clinical Laboratory Studies. Like clinical investigators above, such studies were submitted and reviewed by the FDA at the time of the original PMA approval. Therefore, they add no value and are not pertinent in a reprocessor's submission.
- ❖ Device Characteristics. This information was provided in the original PMA and to supply the same in a reprocessor's submissions would serve no useful purpose.
- ❖ Manufacturing Section. Since the device is not being manufactured by the reprocessor and such information was provided in the original PMA, original manufacturing information is neither available to the reprocessor nor is it relevant.

The inapplicability of the above major elements, all parts of a PMA submission, makes it clear that the kinds of information in a reprocessor's submission for any Class III or Class II device should be the same, and should bear on the important aspects of the reprocessor's operations. These

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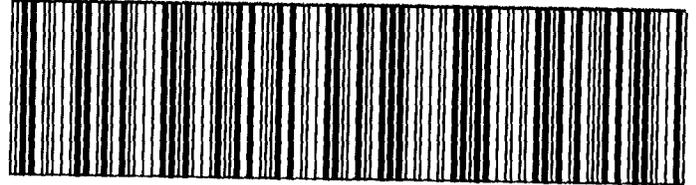
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