

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE

RE: DOCUMENT NUMBER k082150

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. **PAXgene™ Blood RNA System (k042613)**
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the package labeling.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The modifications include:

- addition of an automated RNA extraction device (QIAgen QIAcube®) in addition to a manual extraction method
 - Increase in volume of the elution buffer from 5 mL to 6 mL
 - Modification to the package insert/user's manual to include changing the BR5 buffer volume in the "Kit Contents" table (pg. 5) and amending of the following sections to include the automated protocols in addition to the manual protocols:
 - "Principle and procedure" section (pg. 9)
 - "RNA concentration and purification" section (pg. 12)
 - Additional flowchart added (pg. 13) to show flow of automated protocol
 - "Equipment and Reagents to be supplied by User" (pg. 26)
 - "important Notes" (pg. 27-33)
 - "Automated protocol" section (pg. 40).
 - Summaries of comparisons between the manual and automated methods, kit contents
4. **Comparison Information** (similarities and differences): The differences to the applicant's legally marketed predicate device are listed in #3. The similarities to the applicant's legally marketed predicate device include intend use, sample type, sample volume, overall scientific principle, and RNA extraction reagents.
 5. A **Design Control Activities Summary** which includes:
 - a) Identification of Risk Analysis method used to assess the impact of the modification on the device and its components, and the results of the analysis

The risk analysis method used to assess the impact of the modifications was identified as ISO 14971:2004 (pg. 21). A summary of Design Control activities was included to demonstrate a comparison between the manual and automated methods and any potential affect on RNA yield, purity, integrity, genomic DNA (gDNA) contamination, repeatability, reproducibility, reliability, hands-on time, and total preparation time.

- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied **(Repeatability and Reproducibility Test matrix and Verification and Validation tests, pg. 21-32)**.
- c) A declaration of conformity with design controls. The declaration of conformity should include:

- i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met **(Attachment 6)**, and
- ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review **Attachment 6**).

6. A **Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure**.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.