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| <b>Device Classification Name</b>        | <a href="#">tester, defibrillator</a>                                   |
| <b>510(k) Number</b>                     | K963190   |
| <b>Device Name</b>                       | QA-40M DEFIBRILLATOR TESTER   |
| <b>Applicant</b>                         | METRON U.S., INC.<br>1345 monroe, n.w., #255a<br>grand rapids, MI 49505 |
| <b>Contact</b>                           | jim quinn   |
| <b>Regulation Number</b>                 | <a href="#">870.5325</a>  |
| <b>Classification Product Code</b>       | <a href="#">DRL</a>   |
| <b>Date Received</b>                     | 08/15/1996  |
| <b>Decision Date</b>                     | 07/01/1997  |
| <b>Decision</b>                          | substantially equivalent (SE)   |
| <b>Classification Advisory Committee</b> | Cardiovascular  |
| <b>Review Advisory Committee</b>         | Anesthesiology  |
| <b>statement</b>                         | <a href="#">statement</a>   |
| <b>Type</b>                              | Traditional   |
| <b>Reviewed by Third Party</b>           | No  |
| <b>Expedited Review</b>                  | No  |