

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA**

IN RE: DIGITEK®
PRODUCT LIABILITY LITIGATION

Master Docket No.

MDL No. 1968

PLAINTIFF: _____
(name)

AMENDED DIGITEK® PLAINTIFF FACT SHEET

Please provide the following information for each individual on whose behalf a claim is being made. Please answer every question to the best of your knowledge. In completing this Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. If you are completing the Fact Sheet for someone who has died or who cannot complete the Fact Sheet him/herself, please answer as completely as you can for that person.

The Fact Sheet shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order. A completed Fact Sheet shall be considered interrogatory answers pursuant to Fed. R. Civ. P. 33 and as responses to requests for production pursuant to Fed. R. Civ. P. 34 will be governed by the standards applicable to written discovery under Fed. R. Civ. P. 26 through 37. The questions and requests for production contained in the Fact Sheet are non-objectionable and shall be answered without objection.

In filling out this form, please use the following definition: “healthcare provider” means any hospital, clinic, center, physician’s office, infirmary, medical or diagnostic laboratory, or other facility that provides medical care or advice, and any pharmacy, x-ray department, radiology department, laboratory, physical therapist or physical therapy department, rehabilitation specialist, chiropractor, or other persons or entities involved in the diagnosis, care and/or treatment of you.

In addition, to the extent that the form does not provide enough space to complete your responses or answers, please attach additional sheets as necessary.

I. CASE INFORMATION

1. Please state the following for the civil action that you filed:
 - a. Case caption: _____
 - b. Civil Action Number: _____
 - c. Court in which action was originally filed: _____
 - d. Your attorney:

Name: _____

Address: _____

2. Name of person completing this form: _____
3. Please list any other names you have used or by which you have been known and dates you used those names:

4. Your current address: _____

5. If you are completing this Fact Sheet in a representative capacity (e.g., on behalf of the estate of a deceased person or a minor), please complete the following:

- a. Describe the capacity in which you are representing the individual or estate:

- b. If you were appointed as a representative by a court, state the:

Court Which Appointed You: _____

Date of Appointment: _____

- c. What is your relationship to the individual you represent: _____

- d. If you represent a decedent's estate, state:

Decedent's Date of Death: _____

Address of Place Where Decedent Died: _____

- e. If you are claiming the wrongful death of a family member, identify any and all family members, beneficiaries, heirs or next of kin of that person, including their relationship to Decedent:

THE REST OF THIS FACT SHEET REQUESTS INFORMATION ABOUT THE PERSON WHO PURCHASED, OR PURCHASED AND USED DIGITEK®. WHETHER YOU ARE COMPLETING THIS FACT SHEET FOR YOURSELF OR FOR SOMEONE ELSE, PLEASE ASSUME THAT “YOU” MEANS THE DIGITEK® PURCHASER OR PURCHASER AND USER.

II. CLAIM INFORMATION

1. Name of Digitek® Purchaser/User:

2. Have you used any other names in the last five (5) years? **Yes** ____ **No** ____

If **yes**, please list any such names that you have used:

3. Do you claim that you suffered bodily injuries as a result of taking Digitek®?

Yes ____ **No** ____ If **Yes**, please answer the following:

a. What bodily injuries do you claim resulted from your use of Digitek®?

b. When is the first time you saw a health care provider for any of the symptoms you link to your alleged injury?_____

c. Are you currently experiencing symptoms related to your alleged injury?

Yes ____ **No** ____ If **Yes**, please describe the symptoms:_____

d. Did you see a doctor, clinic or healthcare provider for the bodily injuries or illness listed above?

Yes ____ **No** ____ If **Yes**, who:_____

e. Who diagnosed your injury?_____

f. Date of diagnosis:_____

g. Were you hospitalized?

Yes ____ **No** ____ If **Yes**, please answer the following:

- 1) Date of hospital admission: _____
- 2) Date of discharge: _____
- 3) Hospital name and address: _____

h. What harm or consequence including physical limitations, do you claim you suffered as a result of the bodily injury above, excluding any mental or emotional damages, lost wages or out of pocket expenses listed below?

i. Do you claim that your injury was caused by ingesting defective Digitek® medication?

Yes ___ **No** ___ If **Yes**, please answer the following:

- 1) Describe in detail what you claim the defect to have been in the Digitek® medication that you ingested: _____

- 2) How much of the defective product did you ingest? _____
- 3) When did you ingest the product? _____

j. Have you had any discussions with any doctor or other healthcare provider about whether Digitek® caused you to suffer any illness or injury?

Yes ___ **No** ___ If **Yes**, who: _____

4. Are you claiming mental and/or emotional damages as a result of taking Digitek®?

Yes ___ **No** ___

If **Yes**, what mental and/or emotional damages do you claim resulted from your use of Digitek®?

If **Yes**, for each provider (including but not limited to primary care physicians, psychiatrists, psychologists, and/or counselors) from whom you have sought treatment for psychological, psychiatric or emotional problems, state the following:

NAME	ADDRESS	CONDITION TREATED	DATES TREATED	MEDICATIONS PRESCRIBED

5. Are you making a claim for lost wages or lost earning capacity?

Yes__ **No** ____ If **Yes**, state the annual gross income you derived from your employment for each of the last five (5) years:

6. Have you incurred any out-of-pocket expenses as a result of using Digitek®?

Yes__ **No** ____ If **Yes**, please identify and itemize all out-of-pocket expenses you have incurred: _____

7. What other damages, if any, do you claim you suffered as a result of the purchase or ingestion of Digitek®?

III. DIGITEK® PRESCRIPTION INFORMATION

1. Have you ever used Digitek®? **Yes**__ **No** ____

2. If you answered **yes** to No. 1, identify the following for each period of time during which you took Digitek®:

DOSAGE (.125 MG OR .250 MG)	HOW OFTEN PER DAY OR WEEK?	DATE STARTED	DATE STOPPED	NAME OF PRESCRIBER

3. Name(s) and address(es) of pharmacies where prescriptions were filled: _____

4. Identify the condition for which you were prescribed Digitek®: _____

5. Did you receive any free samples of Digitek®?

Yes __ **No** __ If **Yes**, please state the following:

- a. Who provided the samples? _____
- b. When were samples provided? _____
- c. What was the dosage of the samples? _____
- d. How many samples were provided? _____

6. Do you have in your possession or does your attorney have the packaging from the Digitek® you allegedly purchased, or purchased and used, and/or any Digitek® tablets?

Yes _____ **No** _____

a. If yes, who currently has custody of the Digitek® packaging and/or tablets?

b. If you or your attorney is in possession of tablets, how many do you have? _____

c. Have you or anyone on your behalf tested the Digitek® tablets in your possession?

Yes _____ **No** _____ If **Yes**,

1) Who tested the tablets? _____

2) What test(s) was performed? _____

3) How many tablets were tested? _____

4) When were the tests performed? _____

5) What were the test results? _____

(NOTE: In lieu of answering the following Question Nos. 7a and 7b, please attach a clear copy of the product packaging and/or the label on the vial or blister pack of Digitek® in your or your attorney's possession that provides the information sought below.)

7a. Do you know the lot number(s) for any of the Digitek® you received?

Yes ___ No ___

If Yes, what is/are the lot number(s): _____

7b. Do you know the expiration date for any of the Digitek® you received?

Yes ___ No ___

If Yes, when is/was/were the expiration date(s): _____

8. Have you had any communication, oral or written, with any of the defendants or their representatives?

Yes ___ No ___

If Yes, set forth the date of the communication, the method of communication, the name of the person with whom you communicated, and the substance of the communication between you and any defendants or their representatives:

9. Have you ever used any other digoxin or digitalis product (i.e. Lanoxin)?

Yes ___ No ___

If Yes, please state:

DOSAGE (.125 MG OR .250 MG)	HOW OFTEN PER DAY OR WEEK?	DATE STARTED	DATE STOPPED	NAME OF PRESCRIBER

10. Are you aware that Digitek® was recalled?

Yes ___ No ___ If Yes, please state the following:

a. When you became aware of the recall: _____

b. How you became aware of the recall: _____

11. Did you discuss the recall with any healthcare provider or pharmacist?

Yes ___ No ___ If Yes, please state the following:

a. When that discussion occurred: _____

b. With whom: _____

12. Did you return any Digitek® to Stericycle or any pharmacy?

Yes ___ No ___ If Yes, please state the following:

a. When did you return the product? _____

b. Do you have your paperwork regarding the return? Yes ___ No ___

c. To whom did you return the product? _____

13. Have you ever visited a website, chat-room, message board or other electronic forum containing information or discussion about Digitek®?

Yes ___ No ___ If Yes, please provide the name of the website: _____

IV. MEDICAL BACKGROUND

1. Current Height: _____

2. Current Weight: _____

3. Approximate weight at the time of your injury: _____

4.A. To the best of your knowledge, have you, or any blood-relative family member (child, parent, brother, sister, or grandparent), ever experienced or been diagnosed with any of the following conditions? Please select **Yes** or **No** for each condition. For each condition for which you answer **Yes**, please identify who suffered the condition, you or a relative, and please provide the relative's name and relationship to you. If you suffered the condition, please provide the additional information requested in the table following 4(B):

CONDITION EXPERIENCED OR DIAGNOSED	YES	NO	WHO SUFFERED CONDITION
Abnormal heart rhythm, atrial fibrillation, atrial flutter, ventricular fibrillation, or heart block			
Allergic reaction to medication (e.g., skin reaction, rash, or anaphylaxis)			
Blocked or narrow arteries/plaque buildup/coronary artery disease			
Cardiomyopathy/enlarged heart			
Chest pain/angina			
Congenital heart abnormality			
Congestive heart failure			
Heart attack/MI/myocardial infarction			

CONDITION EXPERIENCED OR DIAGNOSED	YES	NO	WHO SUFFERED CONDITION
High blood pressure/hypertension			
High cholesterol or triglycerides			
Kidney disease or condition			
Stroke/transient ischemic attack/TIA/aneurysm			

4.B. To the best of your knowledge, have you ever experienced or been diagnosed with any of the following conditions? Please select **Yes** or **No** for each condition. If you suffered the condition, please provide the additional information requested in the table following this chart:

CONDITION EXPERIENCED OR DIAGNOSED	YES	NO
Alcoholism or other substance abuse		
Alzheimer's, senility, confusion		
Arthritis (osteoarthritis or rheumatoid arthritis)		
Autoimmune diseases (e.g., rheumatoid arthritis, lupus, Sjogren's, etc.)		
Bleeding or clotting disorders		
Cancer		
Chronic obstructive pulmonary disease/COPD/chronic lung disease/asthma		
Deep vein thrombosis/DVT		
Depression, anxiety, schizophrenia, bipolar disorder		
Dermatologic diseases or conditions		
Diabetes mellitus		
Electrolyte imbalance		
Enlarged prostate, bladder dysfunction		
Gastrointestinal problems (e.g., ulcers, heartburn, acid reflux, GERD, increased or decreased motility)		
Hardening of the arteries/stenosis/aneurysms		
Heart valve problems (e.g., murmur, leaky valve, prolapse, regurgitation)		
Hormonal replacement therapy		
Hypothyroidism/Thyroid condition		
Immune system disease or dysfunction (including HIV or AIDS)		
Liver disorder or disease (cirrhosis, hepatitis, etc.)		
Multiple sclerosis, myasthenia gravis		
Osteoporosis, bone fractures, calcium deficiency		
Peripheral vascular disease or peripheral arterial disease		
Pulmonary embolism/blood clot to the lungs		
Pulmonary hypertension		
Raynaud's syndrome/phenomenon		
Rheumatic Fever/Scarlet Fever		
Tobacco use or addiction		
Vasculitis		

For each condition for which you answered **Yes** in the previous two charts, please provide the information requested below:

DIAGNOSTIC TEST/ INTERVENTION	REASON FOR TEST/ INTERVENTION	DATE	TREATING PHYSICIAN/ HOSPITAL	RESULT OF DIAGNOSTIC TEST/ INTERVENTION

7. Do you now or have you ever smoked tobacco products? **Yes** ___ **No** ___ If **Yes**, please specify the following:

- a. How long have/did you smoke? _____
- b. How much do/did you smoke? _____

8. Did you drink alcohol (beer, wine, etc.) in the three years before your alleged injury?

Yes ___ **No** ___ If **Yes**, please specify the following:

- a. How often did you drink? _____
- b. How much did you drink? _____

9. Have you ever used any illicit drugs of any kind within the five (5) years before, or at any time after, your alleged injury?

Yes ___ **No** ___ If **Yes**, identify the substance(s) and your first and last use: _____

V. ADDITIONAL MEDICATIONS
(INCLUDING OTHER DIGOXIN PRODUCTS, SUCH AS LANOXIN®)

1. For any medications, herbal products or supplements other than Digitek® that you took on a regular basis in the ten (10) years prior to, and at the time of, the incidents described in your Complaint, please provide the information requested below:

NAME OF MEDICATION USED	DOSAGE	PRESCRIBING PHYSICIAN	DATES OF USE	PURPOSE OF PRESCRIPTION

VI. PERSONAL INFORMATION

1. Current Address and Date when you began living at this address: _____

2. Social Security Number: _____

3. Date and Place of Birth: _____

4. Marital Status: _____

If married, spouse's name, occupation and date of marriage: _____

If divorced, dates of the marriage, case name/jurisdiction for the divorce: _____

Has your spouse filed a loss of consortium in this action? **Yes** ___ **No** ___

5. If you have children, please list each child's name and date of birth:

6. For any school attended after High School, please provide the following information:

a. School Name: _____

b. Address: _____

c. Dates attended: _____

d. Diploma/Degree: _____

7. Employment information for the last ten (10) years. Please include employer's name, address, dates of employment, job title, job description and duties:

8. Have you ever served in the military, including the military reserve or National Guard?

Yes ___ **No** ___

If **Yes**, were you ever rejected or discharged from military service for any reason relating to your physical condition? **Yes** ___ **No** ___

If **Yes**, state the condition for which you were rejected or discharged:_____

9. Has any insurance or other company, or Medicare or Medicaid, provided medical coverage to you or paid medical bills on your behalf in the last ten (10) years?

Yes ___ **No** ___ If **Yes**, please specify the following:

a. The name of the company/agency:_____

b. Address:_____

c. Dates of Service:_____

10. Have you applied for workers' compensation (WC) and/or social security disability (SSI or SSD) benefits in the last ten (10) years?

Yes ___ **No** ___ If **Yes**, please specify the following:

a. Type of claim:_____

b. Year application filed:_____

c. Agency where application was filed:_____

d. Nature of disability:_____

e. Time period of disability:_____

11. Have you filed a lawsuit or made a claim in the last ten (10) years, other than in the present suit, relating to any bodily injury?

Yes ___ **No** ___ If **Yes**, please specify the following:

a. Court in which suit/claim filed or made:_____

b. Case/Claim Number:_____

c. Nature of Claim/Injury:_____

12. As an adult, have you been convicted of, or plead guilty to, a felony and/or crime of fraud or dishonesty?

Yes ___ **No** ___ If **Yes**, please set forth where, when and the felony and/or crime:_____

VII. HEALTHCARE PROVIDERS AND PHARMACIES

1. Identify each doctor or other healthcare provider who you have seen for medical care and treatment in the past ten (10) years:

NAME AND SPECIALTY	ADDRESS	REASON FOR VISIT	APPROX DATES/YEARS OF VISITS

2. Identify each hospital, clinic, or healthcare facility where you were hospitalized (in-patient, out-patient, or emergency room visit) in the past ten (10) years:

NAME	ADDRESS	ADMISSION DATE(S)	REASON FOR ADMISSION

3. Identify each pharmacy that has dispensed medication to you in the past ten (10) years:

NAME OF PHARMACY	ADDRESS	APPROX DATES/YEARS YOU USED PHARMACY

VIII. DECEASED INDIVIDUALS AND AUTOPSY INFORMATION

1. If you are filling this out on behalf of an individual who is deceased, please state the following from the Death Certificate of the individual:

(NOTE: In lieu of the following, please attach a copy of the death certificate.)

Date of death: _____
Place of death (city, state and county): _____
Facility or location where death occurred: _____
Name of physician who signed death certificate: _____
Cause of death: _____

If you are filling this out on behalf of an individual who is deceased and on whom an autopsy was performed, please fill in the information below pertaining to the autopsy and the autopsy report:

(NOTE: In lieu of the following, please attach a copy of the autopsy report.)

Date: _____
Performed by: _____
Facility where autopsy was performed: _____
Place where autopsy was performed (city, state, county): _____
Describe any and all tissue preserved: _____

IX. FACT WITNESSES

1. Please identify all persons who you believe possess information concerning your injury(ies) and current medical conditions, other than your healthcare providers, and please state their name address and his/her/their relationship to you:

Name: _____
Address: _____
Relationship to you: _____

Name: _____

Address: _____

Relationship to you: _____

IX. DOCUMENT DEMANDS

1. Authorizations: please sign authorizations that are attached hereto as Exhibit A, for each of the healthcare providers that you have identified above in your Answers to §II, Question Nos. 1-3, and § IV, Question No. 2.
2. Documents in your possession, including writings on paper or in electronic form: If you have any of the following materials in your custody or possession, please attach a copy to this Fact Sheet.
 - a. All documents constituting, concerning or relating to product use instructions, product warnings, package inserts, pharmacy handouts or other materials distributed with or provided to you in connection with your use of Digitek®.
 - b. Copies of the entire packaging, including the box and label, for Digitek® and any Digitek® tablets (plaintiffs or their counsel must maintain the originals of the items requested in this subpart).
 - c. All documents relating to your purchase of Digitek®, including, but not limited to, receipts, prescriptions or records of purchase.
 - d. All photographs, drawing, journals, slides, videos, DVDs or any other media relating to your alleged injury.
 - e. Copies of letters testamentary or letters of administration relating to your status as plaintiff (if applicable).
 - f. Decedent's death certificate and autopsy report (if applicable).
 - g. Medical records, bills, correspondence, reports and all other documents from any health care provider who saw, evaluated or treated Plaintiff/Decedent in the last five (5) years.
 - h. All emergency responder, paramedic or EMT reports regarding Plaintiff/Decedent.
 - i. Documents concerning any communication between Plaintiff/Decedent or Plaintiff/Decedent's attorneys or agents and the FDA or any Defendant regarding the events giving rise to the lawsuit or relating to Digitek.
 - j. Non-privileged documents, including any diaries, calendars or notes that record Plaintiff/Decedent's health, use of Digitek or alleged injuries

X. VERIFICATION

I declare under penalty of perjury that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge. I have supplied all the documents requested in Part ____ of this declaration, to the extent that such documents are in my possession, custody, or control, or in the possession, custody, or control of my lawyers, and supplied the authorizations attached to this declaration.

Further, I acknowledge that I have an obligation to supplement the above responses if I learn that they are in any material respects incomplete or incorrect.

Date: _____

Signature

HIPAA COMPLIANT AUTHORIZATION FOR RELEASE OF EMPLOYMENT INFORMATION

Employee Name:

Identification:

Date of Birth:

Soc. Sec.:

Parents Name/Previous Name(s)

Provider:

(Who is releasing the information)

Requestor:

(to whom the information will be provided)

Name RecordTrak

Address 651 Allendale Road

King of Prussia, PA 19406

I authorize the disclosure of all protected information in any form (including oral, written and electronic) for the purpose of review and evaluation in connection with a legal claim. I expressly request that all entities identified above disclose full and completed protected employment information spanning the time period of **1998 to present**, including, but not limited to, the following:

- All applications for employment, resumes, records of all positions held, job descriptions of positions held, payroll records, W-2 forms and W-4 forms, performance evaluations and reports, statements and reports of fellow employees, attendance records, worker's compensation files, disability records; records submitted in connection with any claims by all physicians, psychologists, psychiatrists, hospital and testing facilities, radiologists, and any and all other health care providers; records of any payments made; records of any litigation resulting from denials of coverage;
- All insurance records, claim forms, renewal records, questionnaires and records of payments made, all insurance policies, and employee benefit records certificates and benefit schedules regarding the insured's coverage, including supplemental coverages; health and physical examination records reviewed for underwriting purposes; questionnaires and records submitted in connection with the applications or renewals;
- All hospital, physician, clinic, infirmary, nurse, psychiatric, psychological and dental records; x-rays, test results, physical examination records and other medical records, medication records;
- All documents related to amendment of any record requested;
- All records pertaining to medical or disability claims, or work-related accidents including correspondence, accident reports, injury reports and incident reports;
- All pension records, disability benefit records, and all records regarding participation in company-sponsored health, dental, life and disability insurance plans; and
- Any other records concerning employment of the Employee named above.

Purpose of Release:

For the purpose of review and evaluation in connection with a legal claim brought by _____.

This authorization expires when the following event occurs: the resolution of litigation. I understand that I may revoke this authorization at any time, except to the extent that action has already been taken in reliance upon it, by giving written notice to RecordTrak. I understand that the covered entity to whom this authorization is directed may not condition treatment, payment, enrollment or eligibility benefits on whether or not I sign the authorization. This information, once it is released, may be re-disclosed by the recipient, and if re-disclosed, the information would no longer be protected by the federal privacy rule. Any facsimile, copy or photocopy of the authorization authorizes you to release the records requested herein.

Signature of Employee if 18 years of age or older _____ Date _____

Signature of Legal Representative _____ Date _____

Relationship to Employee, if not signed by Employee _____

I.

**HIPAA COMPLIANT AUTHORIZATION FOR
RELEASE OF INSURANCE RECORDS
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You are hereby released from any and all liability in connection with disclosure of records, documents, writings and physical evidence to the above firms.

This authorization is effective for one year from this date, or when the following event occurs: Final resolution of the above-identified civil action. Notwithstanding the immediately preceding sentence, I understand that I may revoke this authorization at any time prior to its expiration, except to the extent that action already has been taken in reliance on this authorization, by sending written notice of revocation to RecordTrak. I understand that the entity to whom this authorization is directed, may not condition treatment, payment, enrollment or eligibility benefits on whether or not I sign the authorization.

A copy of this authorization shall have the same force and effect as the original.

Signature of Insured or Insured's Representative Date
Name of Insured:

Former/Alias/Maiden Name of Insured

Insured's Date of Birth

Insured's Social Security Number

Insured's Address

Name of Insured's Representative (if applicable) Description of Authority
to Act for Insured